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IN THE UNITED STATES DISTRICT COURT
 1
               FOR THE NORTHERN DISTRICT OF OHIO
 2
                        EASTERN DIVISION
 3
     IN RE NATIONAL PRESCRIPTION | MDL No. 2804
 4
    OPIATE LITIGATION
                                   Case No. 17-MD-2804
 5
    APPLIES TO ALL CASES
                                  Hon. Dan A. Polster
 6
7
                   Wednesday, April 24, 2019
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10
               CONFIDENTIAL - SUBJECT TO FURTHER
11
                     CONFIDENTIALITY REVIEW
12
13
                            Volume 2
14
15
             VIDEOTAPED DEPOSITION of MATTHEW PERRI, III,
    BS Pharm, Ph.D., RPh, held at Jones Day,
16
     1420 Peachtree Street, N.E., Suite 800, Atlanta,
    Georgia, commencing at 8:35 a.m., on the above date,
17
    before Susan D. Wasilewski, Registered Professional
    Reporter, Certified Realtime Reporter and Certified
18
    Realtime Captioner.
19
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1 2. THE VIDEOGRAPHER: We are now back on the 3 video record with the continued deposition of Matthew Perri. Today's date is April 24th, 2019. 4 5 The time is approximately 8:35 a.m. 6 THE COURT REPORTER: Let me remind you that 7 you are still under oath. 8 THE WITNESS: Thank you. 9 MR. CHALOS: And, Mr. Carter, before you 10 start with your questions, I would like to just 11 say a quick word about our call with Special 12 Master Cohen last night so we get that on the 13 record. 14 Correct me if I get any of this wrong. 15 So we had, last night, shortly before 16 8:00 p.m., a conference call with Special Master 17 Cohen regarding the dispute that arose here 18 yesterday in connection with Mr. Perri's prior 19 opinions in an unrelated case that I believe were 20 memorialized, at least in some part, in Exhibit 10, I think. 21 22 And so the dispute was the extent to which 23 the defendants are entitled to question Mr. Perri 24 about those opinions and about any related 25 opinions he might have in connection with the

```
litigation we're here about today.
 1
 2.
              It was the plaintiffs' position that he
 3
         should not be questioned about opinions as it
 4
         relates to this litigation except to the extent
 5
         he has opinions that are expressed in his report.
 6
              Special Master Cohen ruled that the
 7
         defendants would be entitled to ask Dr. Perri
         about his --
 8
              And I'm sorry I called you Mr. Perri.
              -- that the defendants would be entitled to
10
11
         ask Dr. Perri about the opinions that he
12
         expressed in that prior litigation and they're
13
         entitled to ask whether he has opinions about
14
         those areas in this case with, as I understood
15
         it, the admonishment that if his answer is he
16
         does not have opinions about certain areas in
17
         this litigation, that the witness is not to be
18
         badgered or harassed in any way about those
19
         answers.
20
              So I tried to accurately summarize his
         rulings, and I'm sure defense counsel will
21
22
         correct me if I have not done that.
23
                         I think the only thing the
         defendants have to add is --
24
25
              MR. CHALOS: Can y'all -- can y'all hear
```

```
1
        him?
 2.
                         I think the only thing the
              MR. LADD:
         defendants have to add is that on the call,
 3
 4
         Special Master Cohen did say that the questioning
 5
         defendants have asked so far in no way amounted
         to badgering and the questions so far the
 6
 7
         defendants have asked have been, quote, perfectly
 8
         legitimate.
              MR. CHALOS: Right, and that's, of course,
 9
10
         without the benefit of having read even a rough
11
         transcript at that point. He was relying on the
12
         statements of Counsel in making those rulings.
13
              MS. RODGERS: And one further point: I
14
         think Mr. Chalos agreed, and Special Master Cohen
15
         was on the line, that he would hold the
16
         deposition open through last night.
17
              MR. CHALOS: Yes, that's true, and I
18
         considered it open regardless of the pending
19
         dispute, so we comported ourself accordingly and
20
         consistent with the Ohio rules and other
21
         applicable rules to these proceedings.
22
              MATTHEW PERRI, III, BS Pharm, Ph.D., RPh,
23
      called as a witness by the Track One Defendants,
24
     having been previously duly sworn, continued to
25
      testify as follows:
```

- 1 CROSS-EXAMINATION
- 2 BY MR. CARTER:
- Q. Good morning, Dr. Perri.
- 4 A. Good morning.
- 5 Q. Have you heard the expression in
- 6 marketingspeak that half the money spent on
- 7 marketing is wasted, but the problem is they don't
- 8 know what half?
- 9 A. I have.
- 10 Q. Okay. And that's a quote from earlier in
- 11 the Twentieth Century, correct?
- 12 A. I can't attribute a time to when that
- actually came from, but I do think it is a relic
- 14 from the past, because I think modern marketers are
- a lot smarter, a lot more savvy and sophisticated,
- and if they are wasting half their money, they are
- figuring out why and solving that problem.
- 18 Q. Now, also, in the course of your training in
- marketing, tell me if these numbers sound
- approximately correct to you, that according to
- industry estimates, the average American is exposed
- to between 300 and 1500 advertisements and
- commercials a day.
- What about that, is that consistent?
- 25 A. It sounds about right.

- Q. And then of those, only 80 are consciously
- 2 noted and only 12 result in some form of a response.
- Does that generally track the order of
- 4 magnitude, in your experience?
- 5 A. It -- I think that needs to be qualified,
- though, because the -- the issue of involvement,
- 7 which is a -- kind of a big deal in marketing, and
- 8 it relates to the personal level of connectedness
- 9 you have to an issue. Involvement completely
- 10 changes those numbers.
- So if you're talking about the average
- 12 customer walking down the street, yeah, I could
- agree with those, but if we're talking about
- somebody that is involved in a particular issue,
- such as a disease, somebody who has high blood
- 16 pressure and we're advertising a high blood pressure
- 17 product, you're going to get -- those numbers are
- 18 going to jump way up.
- 19 Q. Would you agree that the quality of a
- 20 product and the services behind it are also
- important keys in the growth of a particular product
- 22 use?
- 23 A. Certainly depending on the category, but
- 24 generally, I would agree with that, and I think
- there's another saying that's from back in the old

- school days that you usually get what you pay for
- and you always get what you don't. So, yes, I would
- 3 agree with that.
- 4 Q. And so even if advertising results in a
- 5 product trial, if people's experience with that is
- 6 not satisfactory or if the services are not up to
- 7 par, advertising is not going to continue -- is not
- 8 going to cause them to continue using something that
- 9 they don't have a good experience with, fair?
- 10 A. When the consumer is in the driver's seat, I
- 11 think that's true, yes.
- 12 Q. Okay. And just because money is spent on
- advertising -- there are plenty of examples of
- 14 expensive marketing campaigns that have been
- 15 failures, correct?
- MR. CHALOS: Object to the form.
- 17 A. I mean, I could think of a few that have
- 18 come to mind in the last decade or two.
- 19 Q. And so while the marketers may be able to
- 20 control some factors -- such as product, price,
- 21 distribution, and forms of production -- those
- 22 factors interact with environmental conditions and
- 23 consumers that the marketer does not have control
- 24 over, correct?
- 25 A. There are -- there are influences in the

- 1 marketplace which marketers do not control, that's
- 2 correct.
- 3 Q. And those environmental conditions and the
- 4 internal decision-making process of the consumer,
- 5 those often dictate the success or failure of a
- advertising and marketing campaign; true?
- 7 A. Yes. I'd like to just add, though, that
- 8 when you mention the environmental factors, I think,
- since we're talking about whether someone is a savvy
- marketer or not, being able to impact, let's say,
- 11 through lobbying -- Coca-Cola can lobby with, you
- 12 know, the State legislature to create a more
- 13 favorable environment. So marketers do go beyond
- 14 the scope sometimes of their internal manipulation
- of variables, but to the external market environment
- as well, so just to make sure that we keep that
- 17 clear.
- 18 O. And so the external environment, in the
- 19 general sense, where they are not interacting with
- it and, again, those -- those factors that they
- don't control, the consumer's response, those are
- 22 key factors that often dictate the success or
- failure of a campaign?
- A. Yes, and I think that the key there, when
- you said dictate the consumer's response, that's why

- the marketer has to do a good job on the production
- side, to make sure that whatever product they are
- 3 creating meets customer needs, because if it
- doesn't, as you pointed out with your question,
- 5 customers won't be loyal to it.
- Q. Do you agree that, in psychological terms,
- 7 people enter the advertising and marketing
- 8 communication process with their perceptual defenses
- 9 up?
- 10 A. In some cases, yes, I would agree with that.
- 11 Q. Do you agree that consumers understand what
- advertising is and they have a skepticism to
- advertising, they know that they are trying to be
- sold a product or a service?
- MR. CHALOS: Object to the form.
- 16 A. Yeah, I think we have to be careful with
- 17 that one, because I think it -- it touches on an
- issue that is very important in healthcare
- advertising, and that is, the knowledge of the
- 20 consumer.
- A lot of times we'll do -- you'll get a
- 22 phone call, a survey or something like that that
- comes on. You're asked a question about a product
- or a service or an experience, and you have no basis
- for making that; yet, people answer anyway.

1 When we apply that to consumer purchases or 2. decision-making or the way they view the 3 advertising, which I think is what you're asking me 4 about, the -- excuse me, the problem is, is if the 5 consumer is not knowledgeable about that area, they 6 don't have a basis to formulate an opinion about 7 whether that should be something that's trustworthy 8 or not. 9 Now, given that, I think sometimes 10 consumers -- and there -- there are different 11 categories of consumers, certainly, but I think 12 sometimes consumers are a bit skeptical about 13 advertising or they're distrustful of it, and that 14 certainly applies to -- specifically to various 15 industries in specific. 16 So I think generally I agree with that, but 17 I think it has -- you have to be careful not to just 18 lump everybody into one basket. 19 Okay. And so with that explanation, let's 20 take it step by step. 21 As a general, broad principle, you agree 22 that consumers typically enter the advertising and 23 marketing communication exchange with their perceptual defenses up, they're -- they're 24 25 recognizing that the communicator is trying to sell

them something, in the general sense? 1 2. MR. CHALOS: Object to the form. 3 Yeah, I -- I think generally that the Α. 4 consumer is going to -- depending on their level of 5 involvement, depending on the level of the impact of the product. 6 7 Just let me give you an example. You --8 you're buying hot dogs for the baseball team to eat 9 after the last game of the season. A lot goes into 10 that decision, and you may see advertising for hot 11 That's a different decision than when you are dogs. 12 buying hot dogs to feed your family on a Tuesday 13 evening. You may see advertising and evaluate it in 14 a different way. 15 So depending on the circumstances, the 16 situation, the level of involvement -- maybe you're 17 not as involved in the baseball team's nutrition as 18 you are your family's nutrition. 19 All of those factors come into play. So 20 while I tend to agree with the general premise of 21 what you're saying, you have to be careful not to 22 just lump everyone into one basket and make the 23 broad characterization that everybody has got their 24 radar on when it comes to advertising because it

depends on the product situation and the -- and the

25

- 1 consumer themselves.
- 2 Some people just have a higher tendency to
- 3 be attentive and to be critical and to be evaluative
- 4 about advertising. Others are just more accepting
- 5 and yielding to whatever they see or hear.
- 6 So generally, I think it's okay to say that,
- 7 but I think you have to be careful and look at the
- 8 specifics of the situation.
- 9 Q. You're actually talking about something
- 10 slightly different, right?
- In the course of purchasing a product or
- service, there are different, like you said, levels
- of engagement; there's -- there's certain purchasing
- decisions that are of greater consequence than
- others. So there are some that people spend a lot
- of time researching and considering, and there's
- others, you know, that they may, kind of, on a whim
- or more automatically, right?
- MR. CHALOS: Object to the form.
- 20 A. So impulse purchases versus purchases
- contemplated, yeah, there are differences between
- those. And again, it may sound like I'm talking
- about something different, but we can't separate
- them because involvement, as a marketing issue, is
- an antecedent of all of these other behaviors that

- we're talking about. So involvement does dictate
- whether or not a consumer is going to be more
- 3 cautious in their interpretation of an ad.
- 4 Involvement does, as you pointed in your remarks,
- 5 impact the way we make our purchasing decision.
- 6 So I just want to be -- I'm not disagreeing
- 7 with you, but I just want to be very careful that we
- 8 don't just blanket say this applies to everybody all
- 9 the time.
- 10 Q. Right. And -- but the one blanket basic
- 11 point that we would make is -- and that I take it
- you'd agree with this -- in general, people
- understand when an -- when they receive an
- 14 advertising communication, that it's trying to sell
- 15 them something --
- MR. CHALOS: Object to the form.
- 17 Q. -- just in the broadest sense?
- MR. CHALOS: Sorry. Object to the form.
- 19 Didn't mean to interrupt.
- A. I hope so.
- Q. And in the context of healthcare, the
- healthcare market, doctors are on the spectrum of
- people -- you know, potential consumers, they are on
- the savvier end, more sophisticated end of potential
- consumers than the run-of-the-mill consumer,

- 1 correct?
- MR. CHALOS: Object to the form.
- A. Yeah. No, I -- unfortunately, doctors are
- 4 people, too, and they suffer from the same problems
- as we do and I think it just depends on the doctor.
- I think some doctors are very sensitive to
- 7 advertising issues. In fact, I know some doctors
- 8 personally that will not see, you know, a sales rep
- 9 and other doctors that they're pretty much fine with
- 10 it.
- 11 So again, in general, I think -- I would
- 12 agree that doctors are more well-educated and they
- should be tuned in to those factors. Can we blanket
- say every doctor is going to be a better consumer
- because of that? I don't think so.
- 16 Q. Okay. Doctors are highly-trained
- 17 professionals, correct?
- 18 A. Yes, they are.
- 19 Q. As a result of their license requirements,
- they are well educated?
- 21 A. They are well educated.
- Q. And you haven't seen any study or research
- that suggests that interaction with advertising
- 24 makes doctors forget their medical training?
- MR. CHALOS: Object to the form.

- 1 A. I can't imagine a study that could measure
- that, but no, I haven't seen anything, no.
- Q. Okay. Are you aware of any research that
- 4 shows that prescription opioid advertising
- 5 manipulates people into acting against their will?
- A. That's a very specific research question,
- 7 and no, I'm not familiar with research that asks
- 8 that specific question.
- 9 Q. Okay. And I think you said that
- 10 yesterday -- but just to be clear, you've not
- interviewed any doctor who prescribed opioids in
- 12 Cuyahoga or Summit County, have you?
- 13 A. As I recall yesterday, I think the way I
- 14 responded to that was that, no, I had not, but I had
- read the testimony of two physicians that worked for
- 16 Ohio Medicaid.
- Q. And you have not interviewed any pharmacists
- in Cuyahoga or Summit County, have you?
- 19 A. No, I have not.
- Q. And you've not interviewed any patient who
- filled a prescription for opioids in Cuyahoga or
- 22 Summit County, have you?
- A. No, I have not.
- 24 Q. Yesterday you said that you would be able to
- indicate depositions that you read cover to cover by

- looking at the list of depositions. Do you have a
- list of the depositions you considered?
- A. Yes. Let me get that.
- Q. As you're getting that, my question will be:
- 5 Please identify for the record the depositions that
- 6 you read word for word.
- 7 MR. CARTER: The witness is reviewing his
- 8 list. We are still here.
- 9 MS. HANNAM: Okay. Great. Thanks.
- 10 A. Okay.
- 11 Q. All right. Tell me what you find.
- 12 A. So to the best of my recollection, these are
- the ones that I read entirely. As I was looking
- 14 through, I saw so many that I have searched through
- and done the specific word searches that I described
- 16 yesterday, but the ones that I've read in entirety
- 17 were Chick and Bingol, Vorsanger, Altier, Snider --
- 18 Q. You might want to go a little slower for the
- 19 court reporter.
- THE WITNESS: I'm sorry. I forgot about
- you. I'll start over.
- 22 A. Chick, Bingol, Vorsanger, Altier, Snyder,
- Vordestrasse, which, as I recall, he doesn't
- 24 pronounce German, he pronounces it Americanly,
- Deem-Eshleman. I can't be 100 percent sure that I

- finished Matt Day, but I think I did -- Matthew Day.
- 2 Gasdia. I'm not sure if it's said Seid, and the
- 3 two, Wharton and Applegate, from Ohio. I know I've
- 4 read substantially Boothe and Wickline, but I don't
- 5 think I've read entirely Wickline.
- 6 Q. All right. Thank you.
- 7 Switching gears, you testified yesterday
- 8 that your review of the marketing messages and
- 9 what's contained in your report, that it doesn't set
- out or, you know, index marketing that you think is
- adjudicated to be improper, false, or misleading
- 12 versus marketing that was appropriate and lawful,
- it's all put together in the aggregate.
- 14 Did I understand that correctly?
- 15 A. Yes. Table II is a listing of all the
- 16 messages that were gleaned from the marketing
- documents, and it is a representative sample of the
- messages that I saw.
- 19 Q. Okay. Now I want to focus on marketing that
- would be considered appropriate and lawful.
- You don't have any opinion criticizing or
- taking issue with expansion of the market
- attributable to lawful or appropriate advertising,
- do you?
- MR. CHALOS: Object to the form.

- 1 A. I think this is the whole crux of the matter
- with regard to marketing and opioids, is that
- 3 expansion of the market for the sake of selling more
- 4 products is not appropriate. And so I think my
- opinions do focus on even the use of appropriate
- 6 marketing to expand the opioid market, because I
- 7 think that's inconsistent with standards that exist
- 8 in the pharmaceutical industry.
- 9 Q. If there is a doctor who has patients who
- need a product and lawful, accurate marketing raises
- 11 his awareness of the availability of a solution for
- 12 his patients and he then redirects his patients to
- that medication that he believes is appropriate,
- exercising his medical judgment, and there was
- nothing false or misleading about that advertising,
- 16 would you suggest that that's an improper expansion
- of the market?
- MR. CHALOS: Object to the form; incomplete
- 19 hypothetical.
- 20 A. So in that very specific scenario, where the
- doctor has identified a patient need and marketing
- has been a positive influence on that, that is
- contributing to legitimate need for opioids, which
- 24 would not require expansion of the market. It
- 25 would -- it would be normal for the market to

- 1 experience that utilization.
- 2 And in addition to that, it's just not that
- 3 simple, because then that doctor has been exposed.
- 4 This information has been encoded into his memory or
- 5 her memory, and on the next occasion for need, that
- 6 can influence that next decision as well.
- 7 So marketing isn't just a one shot, one
- 8 message, one reaction, one outcome. It's about the
- 9 collective nature of all of these messages that are
- 10 compounded and coded into memory, searched for, and
- utilized by doctors in the decision-making process
- and then used either appropriately or
- inappropriately, as the circumstances would dictate.
- And we could -- we could talk about many,
- many specific instances where the utilization might
- 16 be appropriate and the utilization might not be
- 17 appropriate.
- And even in the appropriate situations, some
- of those patients are going to experience problems
- and negative outcomes from the use of opioids.
- Q. What happens downstream when there is a
- legitimate medical prescription? That has nothing
- to do with the propriety of the underlying marketing
- 24 materials, does it?
- MR. CHALOS: Object to the form.

```
1
         Α.
              When we try to correlate a specific
 2.
     marketing message with an outcome, we can do that
 3
     with -- we can try to do that, and we do that
 4
      certainly in marketing to measure its effectiveness.
 5
              But the problem with that is that ignores
      the richness of the information that we have in
 6
 7
      marketing and all of the robust nature of all the
 8
     messages, all the strategies, all the tactics that
 9
     are used.
                 So to try to point your finger at one
10
     message and say that it's directly related to a
11
     downstream outcome, it's almost impossible to do
12
      that without a very narrowly defined, very
13
      intricately designed experiment that was designed to
14
     measure that.
15
              But what we do know about marketing is the
16
      collective nature of marketing results in outcomes,
17
      and I firmly believe and my opinion is that that
18
     marketing is directly related to the downstream
19
     outcomes because it's -- it's encouraging or
20
      discouraging use, it's -- that use then carries with
      it implications. And if marketing caused the use,
21
      then marketing caused the implications as well.
22
23
              The problem I'm having understanding where
         Ο.
     you're going with this is, when you have your
24
25
      aggregate opinion and you say that marketing in the
```

- 1 aggregate leads to various outcomes in the
- aggregate, there is a disconnect between what
- actually happens in the real world. There is no
- 4 doctor exposed to the sum aggregate of that
- 5 marketing that then dictates those outcomes.
- 6 So the situation you're describing in your
- 7 opinions actually never happened on an individual
- 8 level, true?
- 9 MR. CHALOS: Object to the form.
- 10 A. I'd say I disagree with that.
- 11 Q. So how could it? So all -- so there's some
- doctor in some county that saw all of the marketing
- in Table II, and then that dictated their patient
- 14 medical decisions?
- MR. CHALOS: Object to the form.
- 16 A. Yeah, I would probably agree with you that
- there is not a single, solitary doctor that saw
- 18 every single thing. But I would disagree that most
- doctors weren't exposed to multiple forms of
- 20 communication and multiple outreach from the
- 21 marketing of opioids.
- 22 Q. So if there is a doctor that was only --
- that was exposed to multiple marketing messages for
- opioids but the ones that that particular doctor was
- exposed to were all lawful and appropriate

- 1 advertising, how can this aggregate effect that you
- describe, that wouldn't apply to that situation,
- 3 would it?
- 4 MR. CHALOS: Object to the form.
- 5 A. Well, as I think I said earlier, lawful or
- 6 unlawful, the problem is, is with aggressive
- 7 marketing, with the outreach to -- you know, to the
- 8 most highest prescribers, the marketing that I saw
- 9 in this case was designed to increase the size of
- 10 the opioid market. And we see from the results
- 11 manufacturers received, that that's exactly what it
- 12 did.
- So to try to single out a doctor that saw
- only what you describe as the appropriate or
- legitimate messages, I just don't see how that's
- 16 possible because the whole legitimacy of the
- marketing is challenged by the aggressive nature of
- 18 it. So I disagree with your premise that you start
- out with, that there is appropriate marketing that's
- 20 occurring in this arena.
- Q. So you actually disagree with the FDA, you
- think there should be no marketing for opioids?
- MR. CHALOS: Object to the form.
- Q. Even if it conforms to every regulation,
- your opinion is there should never be marketing for

- 1 opioids?
- 2 A. I get to say --
- MR. CHALOS: Object to the form.
- 4 Sorry.
- 5 A. I get to say what my opinions are.
- 6 Q. You do. So am I wrong? Is it --
- 7 A. Yes, you're wrong.
- 8 MR. CHALOS: Hold on. Hold on. Object to
- 9 the form of the question.
- 10 Q. And I'll -- I'll try to not talk over you,
- 11 so let me ask it this way. Is it your opinion to
- the jury in this case that there should not be any
- marketing for opioids?
- 14 A. That is not my opinion, no.
- Okay. So if you believe -- well, let me ask
- 16 the flip side: Do you believe that there is an
- appropriate and lawful place for marketing for
- 18 opioids that should exist?
- 19 A. I think --
- MR. CHALOS: Object to the form.
- 21 Sorry.
- 22 A. I think there can be appropriate marketing
- for opioids, and it would not look like what I've
- seen in this case.
- Q. Okay. So you do believe there could be

- appropriate marketing for opioids and that the goal 1 of that marketing would be to increase product use 2 3 and market share, so how would you -- oh, you 4 disagree? You're shaking your head. 5 MR. CHALOS: Hold on. Don't -- object to the form of the question. 6 7 THE WITNESS: I'm sorry. 8 MR. CHALOS: Don't shake or nod or --9 just --10 THE WITNESS: Okay. 11 MR. CHALOS: Let him finish his question, let me make an objection, if there is one, and 12 13 then please answer. 14 THE WITNESS: Okay. I'm sorry. 15 BY MR. CARTER: 16 Ο. So you were disagreeing with me, so --17 A. Yeah. 18 -- where is the disagreement? Q. Well --19 Α. 20 MR. CHALOS: And object to the form of the previous question. 21 22 Go ahead.
- A. I'm sorry. I'm going to just take a deep
- 24 breath here.
- I don't like it when people tell me what my

- opinions are, because I think I've done a pretty
- 2 good job of laying out exactly what they are and I
- don't go beyond what my opinions are. I'm not going
- 4 to go beyond them. And I think that they are
- 5 completely sound and -- based on what I saw in this
- 6 matter.
- 7 But when you -- when you start saying that I
- 8 don't think there would be any appropriate marketing
- or -- I just -- I can't agree with those things.
- 10 Q. Okay. So there is -- there is appropriate
- 11 marketing for opioids?
- 12 A. And I said there can be appropriate
- marketing, it just wouldn't look like the aggressive
- marketing that we saw here.
- Q. Okay. So is it your opinion that every
- 16 example of marketing you saw was inappropriate?
- 17 A. And this takes us back to why I was shaking
- my head.
- 19 Q. Okay.
- 20 A. The -- my opinion is the marketing must be
- 21 considered in the aggregate. You can't single out
- 22 any single message, you can't single out any single
- contact with a doctor or any single strategy or
- 24 method. You must consider the full scope of the
- 25 marketing.

- 1 Marketing is a process. I have taken great
- lengths to explain that in my report. Marketing is
- 3 something that has an impact that goes beyond the
- 4 incident encounter. It's the sum total of the
- 5 activities.
- 6 Q. Have you ever conducted an academic --
- 7 academic research or study of a category of
- 8 marketing other than opioids where you've -- you've
- only considered the propriety of the marketing in
- the aggregate as opposed to individual messages?
- MR. CHALOS: Object to the form.
- 12 A. If -- I'm not sure I understand your
- 13 question but --
- Q. Sure. Let me ask -- let me -- let me
- 15 withdraw it and ask a different one.
- There can be individual one-off marketing
- messages that are -- that are wrong in any industry,
- 18 correct?
- 19 A. Correct.
- Q. Coca-Cola could release an inappropriate
- 21 commercial?
- 22 A. I mean, I quess as a -- as a hypothetical,
- yeah, that could happen.
- Q. Okay. And just -- if Coca-Cola, you know,
- has an inappropriate, risqué commercial in the Super

- 1 Bowl that gets criticized, that doesn't mean that
- 2 marketing in the aggregate for soft drinks -- that
- 3 wouldn't lead to an opinion on marketing in the
- 4 aggregate for soft drinks, would it?
- 5 MR. CHALOS: Object to the form; incomplete
- 6 hypothetical.
- 7 A. So with that specific example, what I can
- 8 say is, is that if -- you're probably right about
- 9 that, but I can quarantee you that that one
- 10 advertisement that they saw during the Super Bowl
- 11 will impact consumers of Coca-Cola broadly forever.
- 12 It will always be in the customer's mind, and it
- will always be an impact on customers' perceptions
- of Coca-Cola, because that's what marketers work to
- 15 create, is a perception.
- And as I said yesterday and I think I've
- said multiple times during this deposition,
- perceptions are very hard to change and once they're
- changed, they're very durable and stable.
- 20 Q. So just to make sure I understand your
- opinions -- and I'm not, in any way, telling you
- 22 what they are --
- A. Thank you. I apologize.
- 24 Q. -- I'm trying to understand those. So you
- agree that there are and can be appropriate specific

- 1 messages and marketing that can exist for opioids,
- but in this case, you are not looking at that or
- acknowledging that because you think even
- 4 appropriate marketing messages become subsumed
- 5 within an overall aggregate market?
- 6 Explain to me this disconnect between how --
- 7 how you can have appropriate marketing and you
- 8 acknowledge that but then you say that the marketing
- 9 in the aggregate was -- was a problem.
- MR. CHALOS: Object to the form, and also
- incomplete hypothetical.
- 12 A. So I wanted to shake my head again there,
- because instead of telling me what my opinion was,
- 14 you told me what I did or didn't do in this matter,
- and so I want to make it very clear what I did.
- I did look at the marketing. I looked at
- each defendant, and I looked at those defendants so
- that I could form an aggregate opinion about the
- marketing of opioids because that's what is
- impacting our country, is the marketing of opioids
- in the aggregate.
- 22 So the disconnect that -- that I think that
- we're -- we're talking about right now is if there
- 24 were some -- and correct me if I'm wrong here, if
- there were messages out there that were actually

- okay from a science or a research perspective, why
- was the use of those messages inappropriate?
- Is that what your question is?
- Q. That will -- that's one question. I'll ask
- 5 that one.
- So when you look in the aggregate, did you
- 7 see examples of executions in isolation that you
- 8 think were appropriate?
- 9 MR. CHALOS: Object to the form.
- 10 A. So just to remind everybody, I didn't -- I
- 11 didn't evaluate the messages one by one and say, are
- they true or false. There are other experts that
- 13 undertook that task.
- 14 My task was to identify the messages and to
- analyze the marketing. My analysis for the
- 16 marketing was very detailed, very specifically
- 17 planned. It was comprehensive, it was aggressive.
- 18 It utilized the exact techniques that marketers
- 19 would use to maximize the expansion of the market
- 20 and capture market share in instances where that was
- the goal. And I formed my opinions based on that.
- So the question of whether this message or
- this ad was appropriate or not, it wasn't on my
- radar, it wasn't something I was asked to do, and it
- wasn't part of this analysis.

- 1 But whether or not the marketing together
- 2 expanded the market was, and that's exactly what I
- 3 did.
- 4 Q. Okay. So because of your aggregate
- 5 analysis, you are not -- are you prepared to opine
- 6 whether the role and the -- withdrawn.
- 7 I'll rephrase the question.
- 8 Do you have an opinion whether any expansion
- of the market was attributable to lawful
- 10 advertising?
- MR. CHALOS: Object to the form.
- 12 A. You know, this was -- this analysis was not
- designed to be nor was I asked to provide a
- quantitative assessment of the impact of any
- individual ad or collection of ads or messages or
- strategies or tactics. It was to examine the
- 17 aggregate nature of that.
- 18 Q. To the extent the aggregate body of
- 19 advertising and marketing in this space included
- lawful messages, would those lawful messages -- have
- you evaluated the impact of the lawful messages
- versus ones that other experts might consider were
- improper?
- Do you know how the impact compares between
- lawful and improper messages?

- 1 MR. CHALOS: Object to the form.
- 2 A. I think that's what I just answered. Is
- 3 that just a different way of asking me the same
- 4 question?
- 5 Q. I don't understand it to be that, so let me
- 6 ask you, do you -- do you have an expert opinion
- 7 regarding the impact, potential impact of a lawful
- 8 message versus an unlawful message?
- 9 A. So the analysis did not evaluate individual
- 10 ads based on their expected or measured impact in
- 11 the case.
- 12 Q. Okay. And as a principle, it's not an
- opinion that you intend to offer to the jury, is it,
- that misleading ads are more impactful?
- 15 A. Actually, no. I don't -- I don't
- 16 believe -- I don't even believe that. I think that
- the marketing can't be broken down; therefore, the
- positive, constructive, appropriate messages
- 19 combined with whatever messages are determined to be
- false are what impacted this market. And it doesn't
- 21 matter whether it was the good or the bad. They all
- impacted the market, and they impacted the market in
- a way that expanded the market in an inappropriate
- 24 way.
- Q. Okay. So you think the aggregate marketing

- impacted the market in a negative way.
- 2 Am I understanding you correctly?
- MR. CHALOS: Object to the form.
- 4 A. I mean, I want to be more specific if -- if
- 5 I'm going to phrase it that way, but the aggregate
- 6 advertising that was done by the opioid marketers
- 7 expanded the opioid market in a way that was not
- 8 consistent with the standards that have been
- 9 established in the pharmaceutical industry for
- 10 marketing products like that.
- 11 Q. Okay. And so as a -- due to the nature of
- 12 your aggregate opinion, you would fault the
- defendants in this case for the aggregate
- 14 advertising, even including otherwise lawful and
- appropriate messaging?
- MR. CHALOS: Object to the form.
- 17 A. As I've said, I didn't evaluate lawful or
- 18 appropriate. I just identified the advertising.
- 19 And it's my opinion that you can't separate the
- advertising and break it down and look at one piece
- of it and say, was this okay or not and how much
- impact it did have. I don't believe that analysis
- 23 can be done, given -- given what we have to look at
- 24 here.
- Q. Okay. So you have not -- as you've

- 1 explained, you have not undertaken any -- any
- qualitative analysis of what's -- what comprises the
- 3 aggregate market to break it into appropriate or
- 4 inappropriate messages, and your opinion -- you just
- 5 take it all together and say that the aggregate
- 6 created the expansion?
- 7 MR. CHALOS: Object to the form.
- 8 A. And so the first part of that where you said
- you haven't looked at the components of the
- 10 aggregate, or something like that --
- 11 Q. You haven't conducted a qualitative analysis
- 12 as to what percentage of appropriate or
- inappropriate messages comprise that aggregate?
- 14 A. That, I can agree with, yes.
- 15 Q. Okay. All right.
- And so to the extent your opinion is
- 17 critical of the impact of the aggregate marketing,
- do you think that the FDA should ban marketing in
- 19 this space?
- MR. CHALOS: Object to the form.
- 21 A. You know, I -- I don't think I'm the person
- to ask what the FDA should do.
- Q. Okay. Based on your review of the materials
- in this case, any evidence that Walmart ever
- 25 generated primary demand for a prescription opioid?

- 1 MR. CHALOS: Object to the form.
- 2 A. You know, with respect to the case, I think
- 3 the answer is no.
- 4 Q. Okay. I want to talk about your areas of
- 5 expertise. You're not an expert in epidemiology,
- 6 are you?
- 7 A. I use epidemiology in my work all the time,
- 8 but I don't hold myself out as a -- I'm a
- 9 pharmaceutical marketing expert.
- 10 Q. Do you hold yourself out as an expert in
- 11 addiction medicine?
- 12 A. I do not, no.
- Q. Do you hold yourself out as an expert
- 14 historian?
- 15 A. No.
- 16 Q. Do you hold yourself out as an expert in
- interpretation of pharmacy defendant documents?
- 18 A. Is there such a category of expert?
- 19 Q. Well, there was an objection yesterday about
- interpreting documents. So let me ask, do you hold
- yourself out as someone who has some specialized
- training that allows you to describe the meaning and
- intent of internal company documents?
- A. I'm not sure I know how to answer.
- MR. CHALOS: Object to the form. Sorry.

- 1 A. I'm not sure I know how to answer that
- question because I wasn't aware that there was an
- area of expertise called "reviewing expert
- documents, so -- so -- but to that point, I spent
- 5 the last 35 years of my career evaluating literature
- and understanding how to take data and interpret
- 7 that data and then have that -- turn that into an
- 8 article of publication, a book, some other scholarly
- 9 work, and have that be reviewed by others.
- 10 And I've published, you know, literally
- 11 hundreds of times in -- in peer-reviewed space, so I
- guess I have an expertise in that area, if there is
- such an area, but I don't -- I don't really -- I
- 14 mean, I'm an expert in pharmaceutical marketing. In
- order to be an expert in pharmaceutical marketing, I
- have to be able to look at marketing documents,
- understand and interpret, analyze, synthesize the
- data from those documents. So, yeah, I think I'm
- 19 expert in doing that.
- Q. But you don't hold yourself out as an expert
- in divining the intent of an author of a document,
- do you?
- MR. CHALOS: Object to the form.
- A. So as a rule, I can never know what someone
- was thinking. What I can know is what the document

- 1 means in relation to other documents. I can know
- 2 how that document was, perhaps, used or not used. I
- 3 can know what the implications of that document were
- 4 and if any follow-up was done.
- 5 And this is -- this is integral to the case
- 6 study analysis methodology, because in a case study
- 7 analysis, this is what provides the context around
- 8 the solution of the case.
- 9 Q. In 2012, when Ms. Singer first contacted you
- 10 to work on opioid litigation -- I want to focus on
- 11 the time prior to your first contact with
- 12 Ms. Singer. Prior to that, had you published
- anything in peer-reviewed sources related to
- 14 pharmaceutical opioid marketing?
- 15 A. I don't think there were any -- any articles
- that I published during that time period that
- focused specifically on opioids. I know I had
- published several studies on drug utilization in
- 19 general, including use in the elderly, and we
- 20 evaluated a lot of drugs, including opioids, in that
- 21 population.
- I would be happy to tell you about that
- study if you'd like to hear about it, but there was
- 24 a pain or analyesia component to that study. The
- reason I remember that study is because it was

- 1 prior -- just -- just prior to Darvocet being
- 2 removed from the market, and in that study we found
- 3 that you had a 254 percent greater chance of dying
- 4 if you were over the age of 65 and took Darvocet.
- 5 Q. Any other publications prior to Ms. Singer
- 6 contacting you that dealt with the marketing of
- 7 prescription opioid medications?
- 8 A. I think that's the -- yeah, I think that's
- 9 the only study that -- no. I think there was one
- other, but it was, again, focused on the same
- issues, the use of drugs in the nursing home
- 12 population and one component of that was opioids and
- pain -- analgesia in general.
- Q. Prior to Ms. Singer contacting you, had you
- ever undertaken the study of the marketing plans or
- practices of the defendants in this case?
- 17 A. Yes.
- 18 Q. Okay. When did you do that?
- 19 THE WITNESS: Mark, am I allowed to talk
- 20 about other cases that --
- Q. Were you disclosed?
- 22 A. Yes.
- 23 Q. Okay.
- THE WITNESS: Does that mean, yes, I talk
- about it or --

```
MR. CHALOS: Well, yeah. That's -- that's a
 1
 2.
         little bit tricky. I'm not sure exactly what
         case you're talking about but --
 3
 4
              MR. CARTER: Let's table that, and you can
 5
        confer on a break --
              MR. CHALOS: Yeah, let's do that.
 6
 7
              MR. CARTER: -- and figure out how to
 8
        instruct.
 9
              MR. CHALOS: I know there were some cases
10
        where he was disclosed but under a protective
        order, and I'm not sure I've even seen the
11
12
        protective orders in some of those cases but --
13
              MR. CARTER: Okay.
14
             MR. CHALOS: -- we'll -- we'll try to work
        this out.
15
16
             MR. CARTER: Okay.
17
     BY MR. CARTER:
18
             All right. Switching gears, a couple of
19
     odds and ends and then I'll hand off to someone
20
     else.
21
              You mentioned around the end of your tenure
     at Walmart, the beginning of the $4 generic program.
22
23
              Yes, sir.
        Α.
24
             Now, the $4 program at Walmart did not
25
      include controlled substances, CIIs were not in that
```

- 1 program, true?
- 2 A. I'm pretty sure that's true, yes.
- Q. You said yesterday that you did not believe
- 4 you reviewed any documents produced by Walmart in
- 5 this case. You made a reference generally in terms
- of being at a disadvantage because of your material.
- 7 So I just want to ask you: Has that changed
- 8 since yesterday? Have you recalled any
- 9 Walmart-produced documents that you reviewed?
- MR. CHALOS: Object to the form.
- 11 A. I'm glad you said "recalled," because I can
- tell you that when I got home last night, I didn't
- even look at anything, I just went straight to bed,
- 14 but the -- my recollection today is the same as it
- was yesterday. I don't remember seeing a lot of, if
- 16 any, Walmart documents.
- 17 Q. Okay. You mentioned early yesterday morning
- an individual named Nancy Shepherd?
- 19 A. Yes.
- Q. Who is she?
- 21 A. Nancy is the pharmacist in charge of the
- 22 store that I worked, it was Store 2811 in Athens.
- Q. Okay. And where does she currently work?
- 24 A. I think she may be retired now, but she left
- Walmart maybe five or six years ago.

- Q. Do you know the circumstances under which
- 2 she left Walmart?
- 3 A. I do not.
- 4 Q. Why did you reach out to her?
- 5 A. She was the only Walmart -- I know many
- 6 Walmart pharmacists. She was the only one that I
- 7 had in my phone, and so I called her.
- Q. Okay. Now, did you -- when was it that you
- 9 called her?
- 10 A. A month or two ago.
- 11 Q. So by that point, you understood that
- 12 Walmart was a defendant in this case represented by
- 13 counsel, right?
- 14 A. Yes.
- 15 Q. Did you ask anyone for permission to reach
- out to a former Walmart employee?
- MR. CHALOS: Hold on. Object to the form to
- the extent you're talking about communications
- between him and us, which I think are protected.
- But you can -- except for any communications
- you had with lawyers on our side, you can answer.
- 22 A. No, I did not ask for permission --
- 23 Q. Okay.
- 24 A. -- nor did I discuss anything about the
- case. I just asked the question: How did Walmart

- 1 order CIIs? That was it.
- Q. Okay. And was that where the source of your
- information in terms of the Sunday orders?
- 4 A. That was my recollection, but I really
- 5 couldn't recall if we did anything else. And Nancy
- 6 was a long-time Walmart employee, so I figured she
- 7 would be the person to ask.
- 8 Q. When you reached out to Nancy, did you tell
- 9 her why you were calling? Did you say you were
- working as an expert for plaintiffs in litigation
- and wanted some information about Walmart's
- 12 practices?
- 13 A. No. As I just said, I just asked her about
- 14 how CIIs were ordered. And then we talked about my
- new grandbaby, and that was the end of the
- 16 conversation.
- Q. Okay. So when you talked to Ms. Shepherd,
- 18 she -- well, strike that.
- Does Ms. Shepherd know you're working as an
- 20 expert for the plaintiffs in this litigation?
- 21 A. I don't think so, no.
- Q. Other than that question, is there anything
- else you asked her about Walmart or this litigation?
- A. No. I asked her how she was doing, that's
- 25 it.

- 1 Q. Because it was that single question, I take
- it you didn't take any notes from that call?
- 3 A. No.
- Q. Okay. Did you list Ms. Shepherd or that
- 5 conversation in your expert report as a reliance
- 6 material?
- 7 A. No.
- 8 Q. And based on the limited information you
- 9 received from her, I take it you don't rely on that
- for your opinions in this case; is that true?
- 11 A. You know, it's my understanding, as an
- 12 expert, I can -- I can talk to other people about
- what goes on in the industry, and that's all I was
- 14 doing.
- 15 Q. And my question --
- 16 A. Yeah.
- 17 Q. -- with respect, is just: Are you relying
- on that conversation for purposes of your opinions?
- 19 A. No.
- MR. CHALOS: Object to the form.
- Q. Okay. Now, on your CV, you don't include
- the part-time work that you did moonlighting at
- Walmart, do you?
- 24 A. Yes, I do.
- Q. Where in your CV was that?

- 1 A. It's on the first page. It says community
- 2 pharmacy practice, and I worked for a number of
- different employers, so I didn't list them all.
- 4 There just wasn't room.
- 5 Q. Okay. So --
- A. The CV is already 30 some pages long. I'm
- 7 trying to keep it shorter.
- Q. Okay. So Walmart would be listed -- would
- 9 be subsumed within the community pharmacy line of
- 10 your CV?
- 11 A. Yes.
- 12 Q. But Walmart was not identified by name?
- 13 A. Walmart was not. None of the -- none of the
- 14 employers that I've worked for over the years were
- identified by name, and there are a large number of
- 16 them.
- Q. Okay. Do you know that Walmart no longer
- 18 distributes controlled opioids?
- 19 A. That's my understanding, yes.
- Q. Okay. Now, when you worked as a community
- 21 pharmacist, were you aware that opioids posed a risk
- of addiction?
- 23 A. Yes.
- Q. Okay. Were you aware of that back to your
- training as a pharmacist?

- 1 A. Yes.
- Q. And during your time working the counter as
- a community pharmacist at Walmart, did you ever
- 4 violate your corresponding responsibility?
- 5 A. No.
- 6 Q. Okay.
- 7 MR. CARTER: Those are all the questions I
- 8 have for you. Thank you.
- 9 THE WITNESS: Thank you.
- MR. CHALOS: Do you want to stay there? We
- 11 could talk about that issue and then come back
- 12 and --
- MR. CARTER: If you're going to -- if folks
- want to break now; otherwise, do we want to keep
- moving?
- MR. CHALOS: Well, we have to answer your
- 17 question.
- MR. CARTER: Someone -- someone else can
- follow up on that, or however you want to do it.
- 20 I don't --
- MR. CHALOS: That's fine. That's fine. I
- just don't want to have you come back to answer
- those questions.
- 24 MR. CARTER: Yeah. Do folks want to take a
- break or just switch questioners?

```
MS. COATES:
 1
                           Sure.
              MR. CARTER: Okay. We'll take a break.
 2.
 3
              MS. COATES: Yes, the court reporter wants
 4
         to take a break.
 5
              MR. CARTER: All right. We'll take a break.
 6
              THE VIDEOGRAPHER: We are now going off the
 7
         video record. The time is currently 9:34 a.m.
         This is the end of Media Number 1.
 8
             (Recess from 9:34?a.m. until 9:51 a.m.)
 9
10
              THE VIDEOGRAPHER: We are now back on the
         video record with the beginning of Media
11
12
         Number 2. The time is currently 9:51 a.m.
13
     BY MR. CARTER:
14
         Ο.
              I wanted to follow up on the question I
15
     asked regarding whether prior to 2012 you had
16
      reviewed marketing from the defendants, and so
17
     here's my follow-up question: Prior to Ms. Singer
18
      contacting you in 2012, had you ever reviewed
19
     marketing materials from any of the defendants in
20
      this case specifically related to opioid products?
21
              No, I have not.
         Α.
22
              MR. CARTER: All right. Thank you.
              You asked another question that I remembered
23
         Α.
24
      something to.
25
         Q.
              Okay.
```

- 1 A. You were asking about publications prior to
- 2 2012.
- Q. Yes.
- 4 A. The textbook did come out in, I think, 2009,
- or '10, '11, somewhere in there, and it certainly
- 6 doesn't deal with opioids specifically, but it deals
- 7 with all drugs.
- Q. Okay. Does that textbook chapter express
- 9 the opinion that the aggregate effect of opioid
- 10 marketing wrongfully increased the demand?
- 11 A. It doesn't deal with opioids specifically at
- 12 all, so that's not --
- 0. So that's not in there?
- 14 A. It's not in there.
- MR. CARTER: All right. Thank you. No
- 16 further questions from me.
- 17 CROSS-EXAMINATION
- 18 BY MR. TULLY:
- 19 Q. Good morning, Doctor. My name is Josh Tully
- on behalf of Cardinal Health.
- A. Good morning, Josh, Mr. Tully.
- Q. Good morning. Do you know anything about
- 23 Cardinal Health's First Fax Program?
- A. I don't believe so, no.
- Q. Do you know what information was

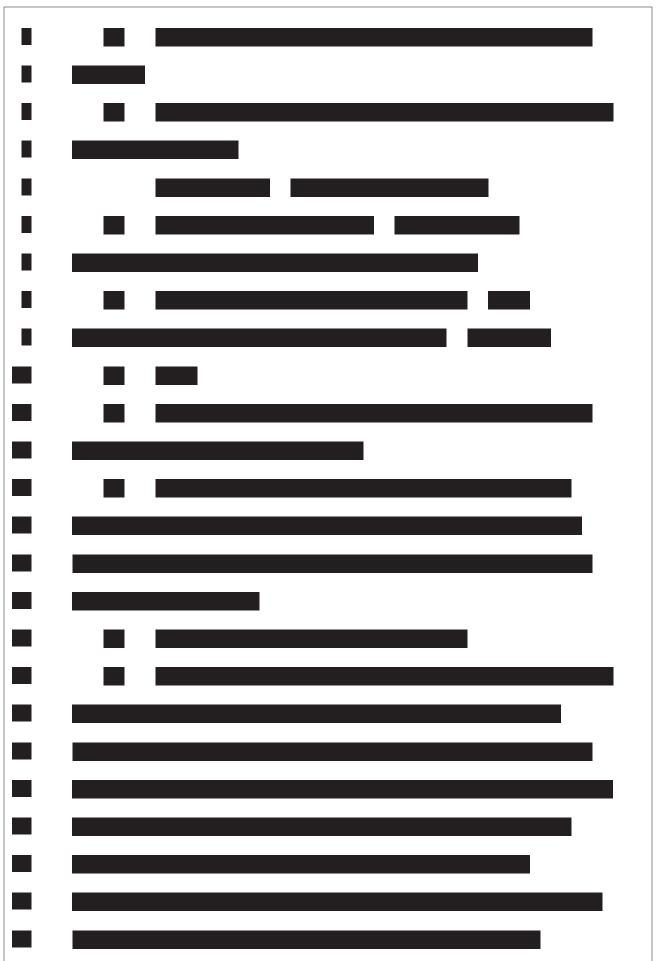
- 1 communicated through that program?
- 2 A. No.
- 3 Q. Do you know the intended audience for that
- 4 program?
- A. As I said, I'm not familiar with it, so, you
- 6 know, I can't help you with that.
- 7 Q. Okay. Do you know anything about Cardinal
- 8 Health's Order Express service?
- 9 A. I can tell you I'm not familiar with any of
- 10 the specific proprietary methods that Cardinal is
- 11 using. I've not -- I've worked in pharmacies that
- ordered from Cardinal before but it's been so long,
- 13 I'm sure that systems have changed. As I said
- 14 yesterday, my last work experience in community
- 15 practice where we would have ordered medications was
- 16 in 2007, so no.
- 17 Q. So I would be correct in concluding that you
- do not -- that you do not know what information was
- 19 communicated through that program, correct?
- 20 A. The first one or the second one that you
- 21 mentioned? The answer is the same for both, no.
- Q. Okay. Do you know what information was
- 23 communicated through Cardinal Health's First Script
- 24 Program?
- A. I don't. That program seems to ring a bell

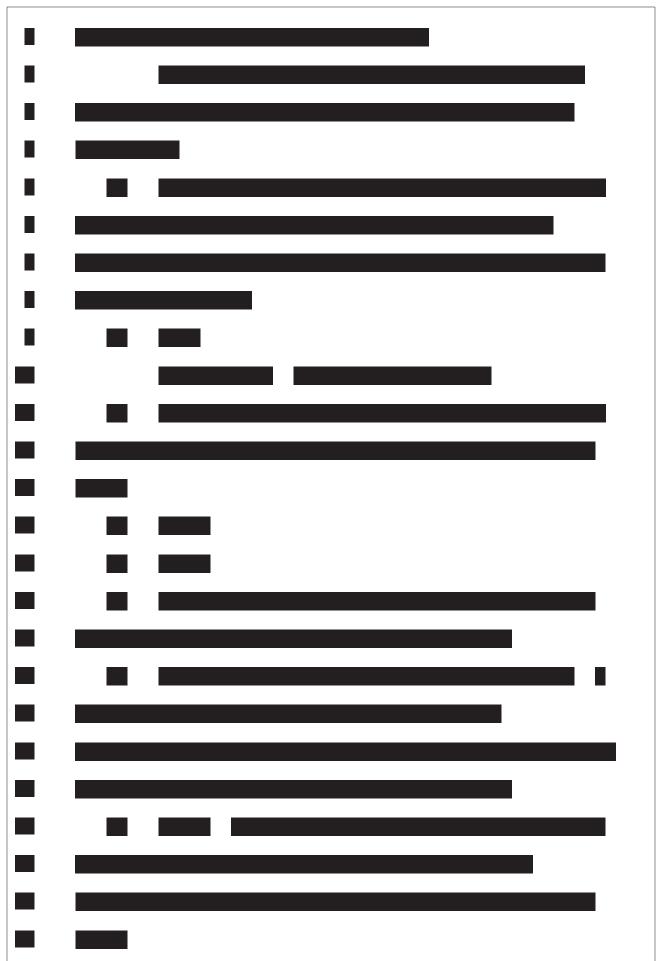
- but I can't say that I know what it was.
- Q. Do you know the intended audience for that
- 3 program?
- 4 A. No.
- 5 Q. Do you know anything about that program?
- A. I don't. As I recall, I thought that that
- 7 was a autostocking program, it could have been
- 8 called something else at the time, but I really, as
- 9 I said, I don't know anything about the proprietary
- 10 services that are offered by Cardinal.
- 11 Q. Okay. I'll just run through a couple more
- 12 here just to confirm that.
- Do you know what information was
- communicated through Cardinal's Rx Deals Program?
- 15 A. Just generally the -- I'm not sure if it was
- 16 related specifically to the generic sourcing, but it
- was just pharmacy supply, pharmacy purchasing
- 18 information.
- 19 Q. Do you know anything else about that
- 20 program?
- 21 A. No.
- Q. Do you know what information was
- communicated through Cardinal Health's Service Flash
- 24 Program?
- 25 A. No.

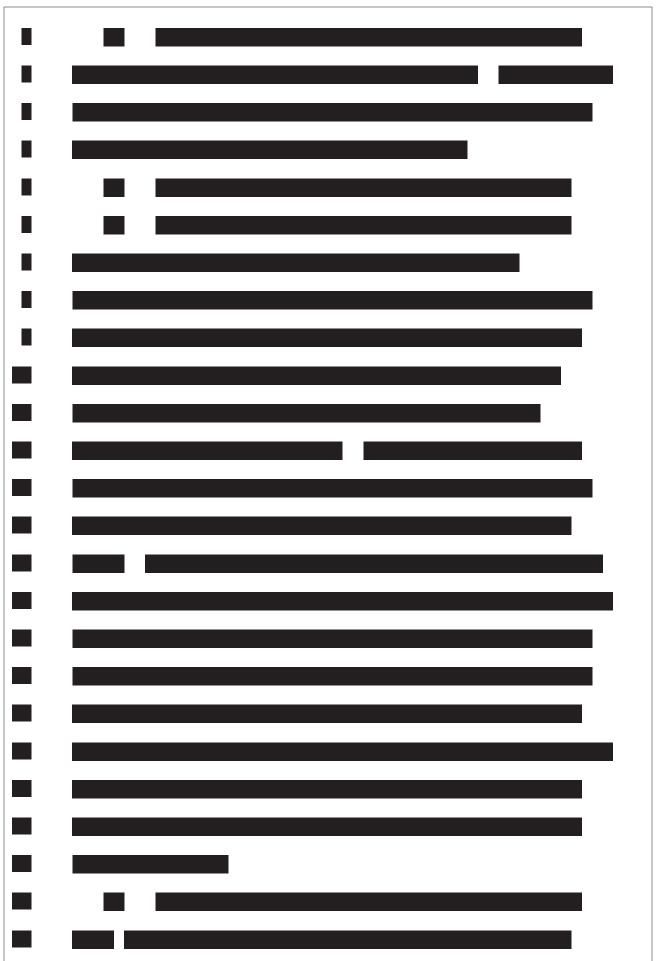
- 1 Q. Do you know the intended audience for that
- program?
- 3 A. I do not.
- 4 Q. Do you know anything about that program?
- 5 A. No.
- 6 Q. Do you know what information was
- 7 communicated through the Pharmacy Health Network?
- 8 A. Nothing specific, no.
- 9 Q. Anything general?
- 10 A. Just that there are programs out there that
- are designed to, you know, provide services to
- independent and smaller chain pharmacies and I think
- that was related to those services, but I can't be
- 14 sure.
- Q. Do you know anything else about that
- 16 program?
- 17 A. No.
- 18 Q. Yesterday Ms. Rodgers asked you some
- 19 questions in connection with a text written by
- Dr. Scott Fishman. Do you remember that?
- 21 A. Yes.
- 22 O. She introduced Exhibit 9 with Bates stamp
- PPLP004086826, which is one of the documents you
- cite in Footnote 371. Do you remember that?
- 25 A. I think we still have it here. So I have

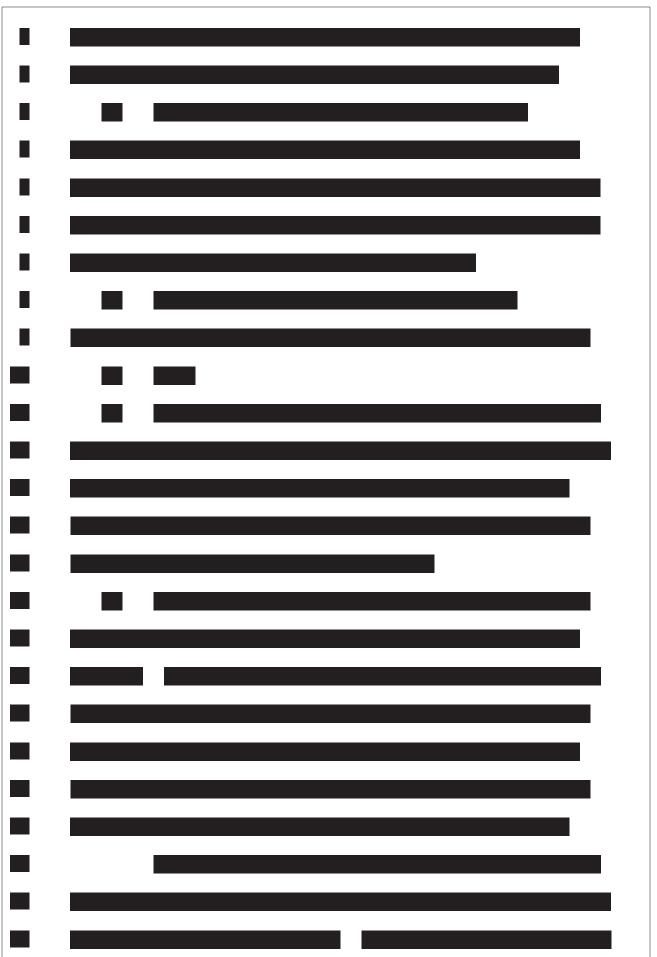
- 1 here Exhibit 9 in front of me.
- Q. Okay. In Footnote 371 you cite two other
- documents which I will provide you copies of. The
- 4 first one is Bates stamped CAH MDL2804 00846989,
- 5 which I will mark as Exhibit 11.
- 6 (Perri Exhibit 11 was marked for
- 7 identification.)
- 8 BY MR. TULLY:
- 9 A. Give it a good push. Thank you.
- 10 Q. The second document you cite in Footnote 371
- bears Bates stamp CAH MDL2804 00866121, which I will
- mark as Exhibit 12.
- 13 (Perri Exhibit 12 was marked for
- identification.)
- 15 BY MR. TULLY:
- 16 Q. So now you have copies of all three
- documents that you cite in Footnote 371, correct?
- 18 A. Yes, I do.
- 19 Q. You're welcome to review those documents
- 20 before I ask you some questions about them, just let
- 21 me know when you're ready.
- 22 A. Okay. Okay.

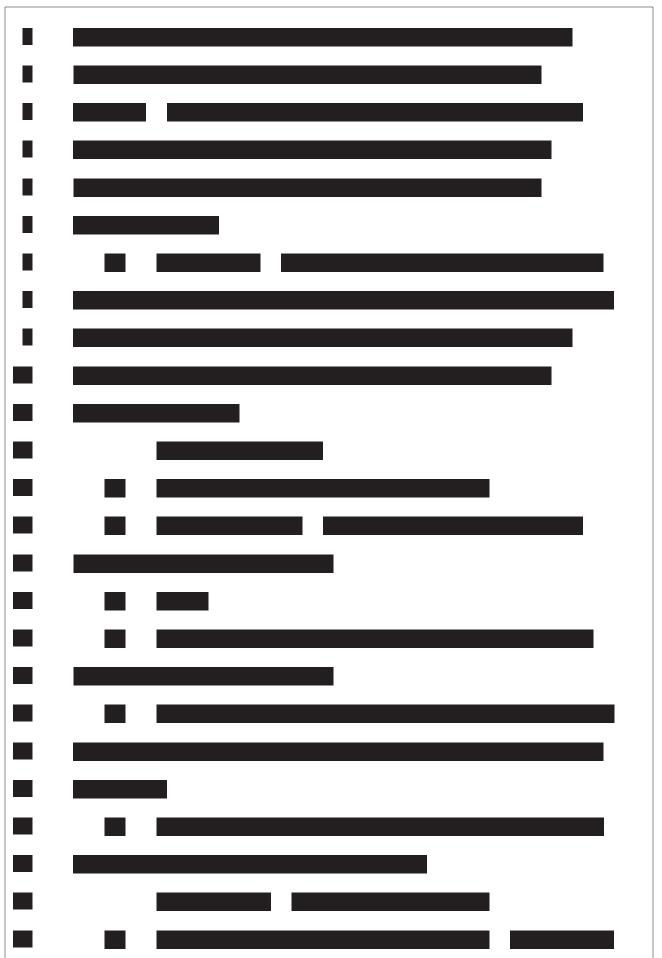


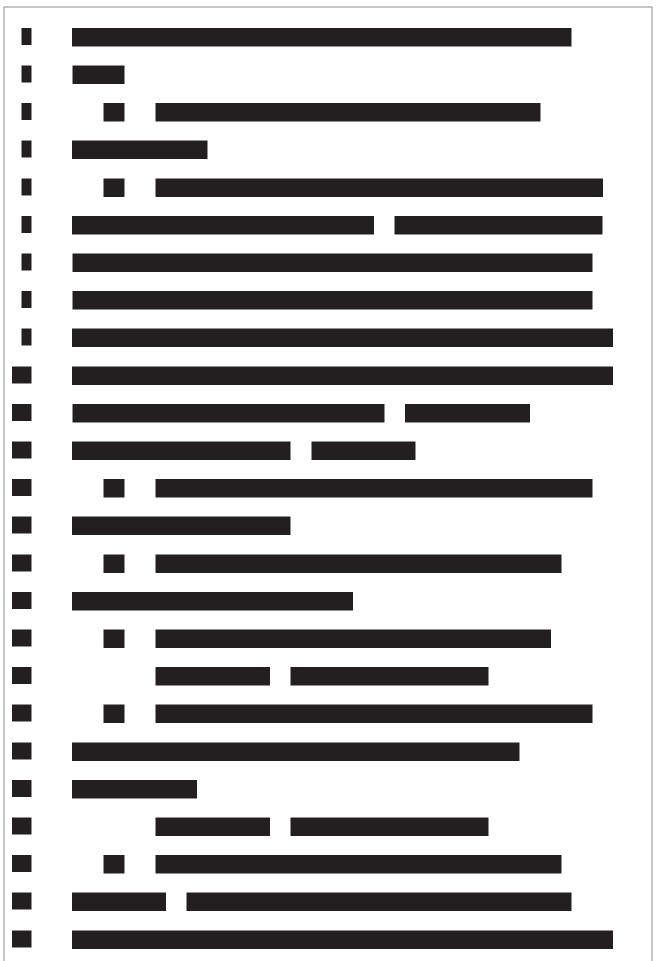


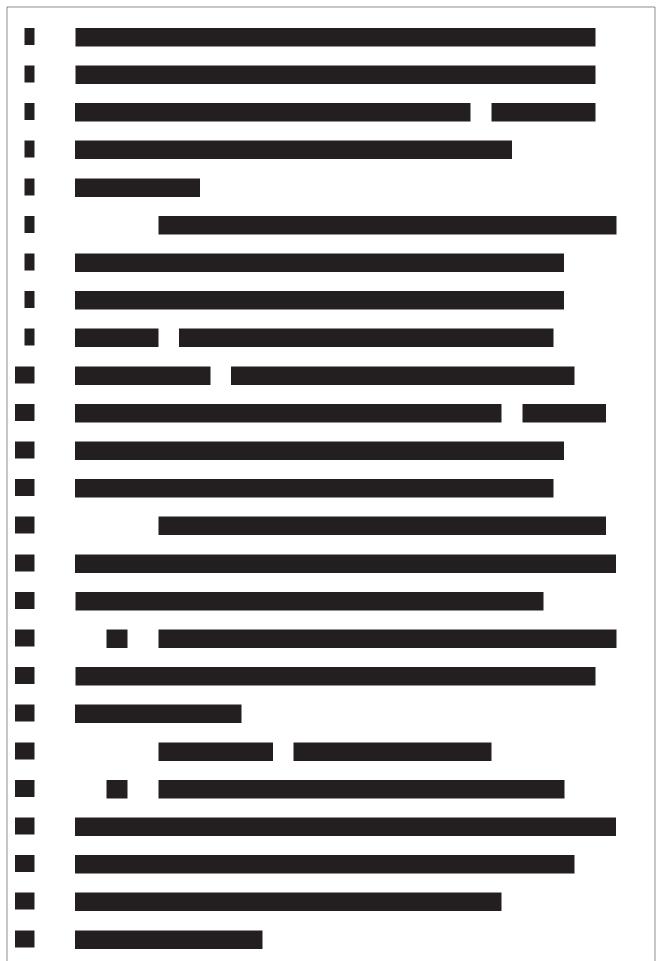


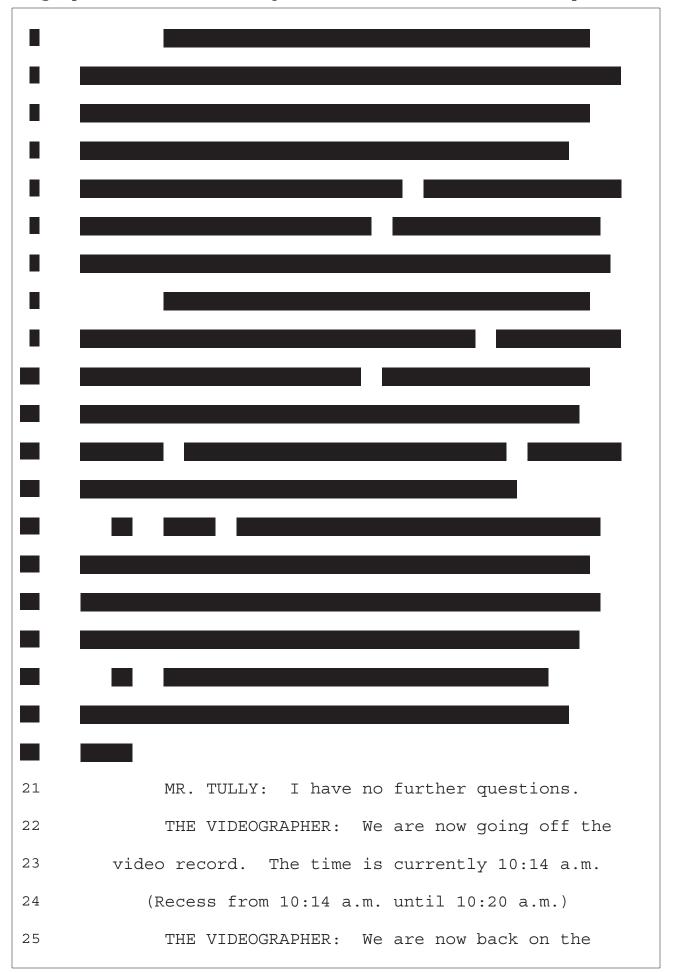












- video record. The time is currently 10:20 a.m.
 - 2 CROSS-EXAMINATION
 - 3 BY MR. GALIN:
 - 4 Q. Dr. Perri, my name is Ross Galin. I'm from
 - 5 O'Melveny & Myers and I represent Janssen and J&J in
 - 6 this matter. I would say nice to meet you but we've
- 7 been sitting beside each other for many hours now.
- Bear with me, if you would. I am going to
- 9 attempt to streamline my questions for you that will
- 10 most likely result in a fair amount of me fumbling
- about trying to put jigsaw pieces together after
- having crossed stuff out that my colleagues have
- already asked you about, so I apologize if I'm
- 14 fumbling about, but I do want to preserve some of
- their time and your time and don't want to retread
- 16 ground.
- 17 But with that said, there is a -- there are
- a couple of pieces of retreading, ground to be
- retread just briefly to set the parameters.
- Am I correct, based on what I have heard in
- your testimony so far, that you are not offering any
- Janssen-specific opinions in your report or
- 23 testimony?
- 24 A. Yes, that's correct. The opinions are not
- specific to any one defendant, and that includes all

- defendants. They are general aggregate opinions
- about all of the defendants in this matter.
- Q. Okay. And if called to testify at trial,
- 4 you will not be offering any Janssen-specific
- opinions; is that correct?
- A. Yes, that is correct.
- 7 MR. CHALOS: Object to the form.
- 8 A. That's correct.
- 9 Q. Another point that has come up repeatedly,
- 10 so I apologize but I'm doing my housekeeping: You
- 11 have no opinions that you are offering as to whether
- 12 any Janssen marketing claims are false or
- misleading; is that correct?
- 14 A. That's correct. The assessment of the false
- and misleading nature of the ads was done by other
- 16 experts.
- 17 Q. And consistent with that, my understanding,
- based on your testimony in this matter so far, is
- 19 that to the degree that you are making
- determinations about false or misleading, it is
- 21 based on reliance on -- I believe you listed five
- other experts retained by plaintiffs in this matter;
- is that correct?
- 24 A. Yes. There was one additional. It was the
- FDA warning letters as well, so -- but you're

- 1 correct in the five other experts.
- Q. And is there a particular FDA warning letter
- directed at Janssen on which you are relying?
- 4 A. I don't want to take your time now to look
- 5 through here. I don't recall -- somewhere in the
- 6 report there is a list of the specific warning
- 7 letters. I can't recall if there was a Nucynta
- 8 letter or not.
- 9 Q. Okay.
- 10 A. I want to leave that open that I can correct
- 11 that when I figure that out.
- 12 Q. Well, how about if we -- are you willing to
- agree that if the warning letter is not listed in
- the report, in this section, it is not something
- 15 you're relying on?
- 16 A. Yes.
- 17 Q. Okay. Let me apologize up front again for
- what will be something of a slog here, but I just
- 19 want to go through this. Can I ask you to look at
- 20 Exhibit 1, which is your report, as you are
- 21 familiar.
- 22 A. Yes.
- Q. And if I could ask you to turn to Table II
- 24 on Page 86.
- 25 A. I'm there.

- Q. Okay. Now that I've done that, I'm actually
- 2 going to -- well, first, you've testified several
- 3 times that what the table reflects is messages that
- 4 you've seen, representative messages across the
- 5 various defendants in this case, put into various
- 6 categories that are listed A through X, correct?
- 7 A. Correct.
- 8 Q. Okay. Can I ask you to skip to Page 92, if
- 9 you would, and we'll begin our little bit of a slog
- 10 here, which is to say you see D on Page 92 is:
- "Minimize concerns about addictive nature of
- 12 opioids."
- And 90 -- and D covers Pages 92 to 93 in
- 14 your report, correct?
- 15 A. Yes.
- Q. Am I correct that you do not list any
- 17 Janssen documents in this section of the table?
- 18 A. In Part D of Table II I do not see any
- 19 Janssen documents.
- Q. Okay. Can I ask you to look below that in
- Letter E? It reads: "Science now showing opioids
- are not as addictive as once thought."
- 23 Is that correct?
- 24 A. That's correct.
- Q. And there are three documents listed in

- 1 Section E of the table, correct?
- 2 A. Yes.
- Q. None is a Janssen document, correct?
- 4 A. That's correct.
- Q. Okay. If we turn to Page 100, H: "Problems
- only occur when opioids are abused or used
- 7 illegally addicts are bad people who knowingly
- 8 abuse the drugs, not good people who were seeking
- 9 treatment for legitimate ailments."
- 10 Did I read that correctly?
- 11 A. Yes.
- 12 Q. And the documents listed under H span from
- Page 100 of the report into Page 101; is that
- 14 correct?
- 15 A. It is.
- 16 Q. And no Janssen document is listed there,
- 17 correct, in that section, correct?
- 18 A. That's correct.
- 19 Q. Okay. And if we go down to -- if we move
- ahead to Page 111 -- you're probably picking up on
- 21 the theme here.
- 22 A. Yes.
- Q. Letter N, that category is: "Even patients
- 24 at high risk of addiction can be safely prescribed
- opioids by using risk-mitigation strategies such as

- 1 pain contracts."
- Did I read that correctly?
- 3 A. Yes.
- 4 Q. And that letter, the documents under Letter
- N span from Page 111 into Page 112, correct?
- 6 A. Yes.
- 7 Q. And again, am I correct that there are no
- 8 Janssen documents listed in this portion of the
- 9 table?
- 10 A. You are correct.
- 11 Q. Okay. If we could move ahead to Page 114,
- 12 I'll direct your attention to Letter P:
- "Undertreated pain should be treated with opioids."
- 14 Did I read that correctly?
- 15 A. Yes.
- Q. Okay. And P spans from 114 to the top of
- 17 Page 116; is that correct?
- 18 A. Yes.
- 19 Q. And am I correct that, again, no Janssen
- documents are listed in this section of the report?
- 21 A. You are correct.
- Q. Okay. Page 116, Q: "There is more risk of
- leaving pain untreated than using opioids to treat
- 24 pain. "
- Did I read that correctly?

- 1 A. Yes.
- Q. And Q lasts all the way to Page 118?
- 3 A. Yes.
- 4 Q. Okay. And am I correct that there are no
- 5 Janssen documents listed in that section of this
- 6 report as well?
- 7 A. Yes, you are.
- 8 Q. Okay. And below on Page 118, R is:
- 9 "Opioids offer more effective pain control and are
- 10 safer than alternatives."
- And I believe that is only on Page 118. Am
- 12 I correct that under Letter R there are no Janssen
- documents listed?
- 14 A. Yes, you are.
- 15 Q. Okay. We could go ahead to Page 123, easier
- said than done for me, apparently. At the bottom of
- 17 123, Letter U is: "Opioids can be prescribed for
- any pain condition without risk."
- 19 Did I read that correctly?
- 20 A. You did.
- Q. And Section U, so to speak, runs from 123 to
- the top of 125; is that correct?
- 23 A. Yes.
- Q. And again, no Janssen documents are listed
- in that section of the table, correct?

- 1 A. Yes.
- Q. Okay. Also on Page 125, there are two
- documents listed under V, which is: "Opioids can be
- 4 prescribed to any age group without risk."
- Is that correct?
- 6 A. Yes, sir.
- 7 Q. And again am I correct that neither of the
- 8 documents are Janssen documents?
- 9 A. You are.
- 10 Q. All right. And good news, I get to say
- 11 finally, on Page 125, W is: "'Round the clock'
- dosing should be used for chronic pain rather than
- 'as needed' dosing."
- And W runs from 125 to Page 126; is that
- 15 correct?
- 16 A. That is correct.
- 17 Q. And am I correct that there are no Janssen
- documents listed in that section?
- 19 A. Yes, you are.
- Q. All right. Thank you. Dr. Perri, I just
- want to ask you a couple of questions or a few
- 22 questions.
- Do you agree that chronic pain is a serious
- 24 medical condition?
- MR. CHALOS: Object to the form.

- A. So it's -- of course it's out -- that's
- outside the scope of what I did here, but as a
- 3 pharmacist, I would agree that chronic pain is
- 4 serious, yes.
- 5 Q. Okay. And will you agree with me that
- 6 chronic pain affects millions of people in the
- 7 United States?
- 8 MR. CHALOS: Object to the form.
- 9 A. If you have a statistic, I'd be happy to
- 10 entertain it. I don't -- I don't follow the
- 11 numbers, so I can't say that it affects millions or
- tens of millions, I just don't know, but I agree
- it's a serious problem and a lot of people are
- 14 affected.
- 15 Q. Okay. And will you agree with me that
- 16 chronic pain affects people in Summit County, Ohio
- 17 and Cuyahoga County, Ohio?
- MR. CHALOS: Object to the form.
- 19 A. Certainly, yes.
- Q. Okay. Will you agree with me that there are
- risks associated with untreated chronic pain?
- MR. CHALOS: Object to the form.
- 23 A. So I have to be real careful here because I
- don't -- I don't want to, you know, go beyond my
- ability to have a basis for knowing that, and I'm

- not a doctor and so I can't really evaluate what
- 2 patients face for not being treated for pain, and I
- 3 think there are other experts that are better suited
- 4 to answer that question.
- 5 Q. So if I were to ask you questions, as I have
- been to a degree, about the treatment of pain, is it
- your position that your answers would be that you
- 8 are not an expert and able to answer those
- 9 questions?
- 10 A. Yeah, I'm not an expert on pain management,
- so I don't hold myself out as one and I -- I am a
- pharmacist, so I've provided care to patients who
- are in pain, but it's very different than diagnosing
- and following and monitoring and caring for a
- patient over a long period of time who has chronic
- 16 pain.
- Q. Okay. Well, would you agree with me that
- it's the role of the prescribing physician to weigh
- the risks and benefits of any pain medications when
- treating an individual with pain patient?
- 21 A. Yes, I would, I would agree with that
- 22 statement.
- Q. Okay. Would you agree with me that for some
- 24 patients opioids may be the only effective treatment
- 25 for chronic noncancer pain?

```
MR. CHALOS: Object to the form; also
 1
 2.
        outside the scope of his opinions.
 3
        Α.
              You know, again, the -- to talk about these
 4
     kinds of issues -- I realize it's important for you
 5
     to do that and I want to try to give you an answer,
     but I have to qualify it and say that, you know,
 6
 7
      this is not what I did in my analysis here. I can
 8
     answer that question as a pharmacist, and -- you
 9
     know, so given that, my sentiment about that is, is
10
      that that's a downstream conclusion. When a patient
11
      is first starting out, there are always alternatives
12
      and it may end up that some of those patients end up
13
      that an opioid is the only alternative, I agree with
14
      that, but at the beginning of care -- and there's a
15
      lot of -- a lot of the messages in these tables that
16
     we just went through focused on using opioids sooner
17
      in the disease process, using them preferentially.
18
              So I think I want to be real careful and
      just say that the end result, it's possible that
19
20
      opioids might be the only alternative for a patient,
     but getting to that point, it's -- that's definitely
21
22
     not true.
23
              Okay. Thank you. Dr. Perri, you've said in
24
      some form throughout your testimony over the last
25
      day, and now a quarter, so -- that there is a drug
```

- 1 problem in this country. And am I correct that
- you've testified in this deposition that there is a
- drug problem in this country?
- 4 MR. CHALOS: Object to the form.
- 5 A. I know we've talked about that. I believe
- 6 that there is a drug problem in this country, yes.
- 7 Q. Okay. And I take it you believe there --
- 8 well, I'll just ask you.
- 9 Do you believe there is a drug problem in
- 10 Cuyahoga County?
- 11 A. I think it exists everywhere in the United
- 12 States, and probably other places in the world too.
- Q. Okay. And do you believe that drug problem
- 14 involves heroin?
- MR. CHALOS: Object to the form; beyond the
- scope of his opinions here.
- 17 A. So, you know, I mentioned earlier I'm not an
- 18 expert in pain management, and I'm also not an
- 19 expert on addiction. I've done some work in the
- 20 area, so I'm familiar with -- I've published in the
- area of opioids, so I've read a lot of literature
- 22 about it, but, you know, I didn't -- I didn't look
- at anything in my review of this case that focused
- on illicit drug utilization. I was completely
- focused on the prescription opioid market.

- 1 Q. I'll just ask this one last question: Do
- you believe that the drug problem in this country
- 3 that you've referred to predates the 1990s and the
- 4 growth that you've discussed of opioids?
- 5 MR. CHALOS: Object to the form.
- 6 A. So I didn't -- I didn't really do a
- 7 historical review, and I know -- I know another
- 8 expert did, so I think we can defer to that expert
- 9 to get an answer to that question.
- I think the data that I did see, the data
- 11 points that were identified through my analysis of
- the marketing of defendants certainly indicate that
- there was a point in time in the mid '90s where the
- opioid utilization began to increase rapidly and
- sustainably for many years, and alongside that there
- 16 was a parallel track of a growing, you know,
- 17 national, literally, catastrophe about drug use.
- And so with that background and caveat that
- 19 I'm not a historian, I think that's about as much as
- 20 I can stay about it.
- Q. Okay. I'm going to try to get the payoff
- 22 now from all this premarking we did.
- MR. CHALOS: Wait, I thought that was just
- your one last question.
- MR. GALIN: Only on that. The judge I

clerked for, by the way, always said never trust 1 2. a lawyer who tells you he only has one question. 3 MR. CHALOS: That one question in 86 parts. 4 MR. GALIN: Yeah. That's the old Rodney 5 Dangerfield. (Perri Exhibit 13 was marked for 6 identification.) 7 BY MR. GALIN: 8 I'm going to show you what has been 9 Ο. 10 premarked as Exhibit 13. MR. GALIN: I'll throw those over. I 11 12 suppose if I were more adept, I would use the 13 Elmo now, but I think that's probably only going 14 to make this --15 MR. CHALOS: Are they both the same? 16 MR. GALIN: Yes. Yeah. 17 MR. CHALOS: Okay. 18 MR. GALIN: That's only going to make things 19 last longer. 20 BY MR. GALIN: 21 Dr. Perri, do you recognize this document? Q. 22 Α. Yes, I do. 23 O. What is this? Duragesic package insert. 24 A. 25 This is the FDA-approved package insert for Q.

- 1 Duragesic?
- 2 A. It appears to be, yes.
- Q. Okay. And because I don't believe the date
- 4 is on here --
- 5 A. 1990.
- Q. There you go. I'm glad you found it,
- 7 because I didn't. It is the 1990 insert?
- 8 A. Uh-huh.
- 9 Q. Could you read for me below the Duragesic,
- 10 the header, the first thing that is stated on the
- 11 label?
- 12 A. "Fentanyl transdermal system."
- Q. Okay. And then, I'm sorry, right below
- 14 that?
- 15 A. "Warning: May be habit forming."
- Q. Okay. Can I ask you to turn to -- I
- apologize, the page numbers aren't numbered but to
- 18 -- if you go one, two -- three pages in. I
- 19 recognize that they are double-sided. I'm talking
- about the actual page rather than the page number.
- 21 At the top of the page it says "Chronic Pulmonary
- 22 Disease."
- 23 A. Yes.
- Q. Okay. We're on the same page. I'll give
- your attorneys a chance to make sure that they are

- there.

 MR. CHALOS: I lost you. Three pages in?

 MR. GALIN: It's three full pages, not on

 both. The top is "Chronic Pulmonary Disease."
 - MR. CHALOS: Oh, the back of the third page.
 - 6 MR. GALIN: Yeah.
 - 7 MR. CHALOS: Okay. Got it. I'm there.
 - 8 MR. GALIN: Later, when we have section
 - 9 numbers, it will get a lot easier.
- 10 MR. GALIN:
- 11 Q. If I were to direct your attention about
- just halfway down, do you see in there that it's
- Drug or Abuse [sic] Dependence, that section?
- 14 A. I do.
- Q. All right. Would you mind reading the text
- 16 under that header for me?
- 17 A. "Use of Duragesic in combination with
- 18 alcoholic beverages and/or other CNS depressants can
- 19 result in increased risk to the patient. Duragesic
- should be used with caution in individuals who have
- a history of drug or alcohol abuse, especially if
- they are outside a medically controlled
- 23 environment."
- Q. Can we flip over a page now? Again I'm
- using pages. It's about two pages of text beyond.

- 1 You see at the top there is a section "Drug Abuse
- and Dependence."
- 3 A. Yes.
- Q. Okay. To be fair, I'll bear the brunt of
- 5 reading at this point. It says: "Fentanyl is a
- 6 Schedule II controlled substance and can produce
- 7 drug dependence similar to that produced by
- 8 morphine. Duragesic therefore has the potential for
- 9 abuse."
- 10 Did I read that correctly?
- 11 A. Yes, you did.
- 12 Q. Okay. I believe, but let me confirm, that
- is all I'd like with this exhibit, so you can set
- 14 that one aside.
- 15 (Perri Exhibit 14 was marked for
- 16 identification.)
- 17 BY MR. CHALOS:
- 18 Q. I am now going to show you what has been
- marked as Exhibit 14. I'll throw that and try not
- to wound anyone. These get thicker by the moment.
- MR. CHALOS: Wait. 14?
- MR. GALIN: Yes.
- MR. CHALOS: This one was --
- MR. GALIN: That was 13.
- MR. CHALOS: Oh, okay. Thank you.

- 1 BY MR. GALIN:
- Q. Dr. Perri, do you recognize this document?
- 3 A. This a later package insert, prescribing
- 4 information, for Duragesic as well.
- 5 Q. All right. And maybe you've identified the
- date on your own, but if not, I will represent to
- you that this is the 2005 Duragesic package insert.
- 8 A. Actually, is it 2005? I thought it was
- 9 earlier than that. Yeah, it's 2003.
- 10 Q. Yes, this is 2003. Excuse me. I apologize.
- I think this is actually the one that was in effect
- in '05 but was modified in '03.
- 13 A. Yes.
- Q. So just so that we're clear, just so you're
- aware, I'm showing you from what was in effect in
- 16 '05 but was approved in '03.
- 17 A. Yes.
- 18 Q. Do you recognize -- I'll just -- on the
- 19 front page of this you see that there is text that
- is inside a black outlined box that continues on to
- 21 Page 2 of the label?
- 22 A. I see that.
- Q. And am I correct this is what is typically
- referred to as a black box warning?
- A. You're correct.

- Q. What is a black box warning, Dr. Perri?
- 2 A. It is a -- in my mind, the way I consider a
- 3 black box warning is a flag that goes up that says,
- 4 hey, be careful with this drug because it has some
- 5 special considerations that people need to know
- about before they prescribe it. It doesn't mean
- 7 don't use it, it doesn't mean that using it is going
- 8 to have a negative outcome automatically. It just
- 9 means be aware, prepare the patient for whatever
- 10 potential could befall them, make sure they are
- 11 ready to deal with anything that could come up, and
- that the prescriber, the pharmacist, anyone involved
- in their care is aware of the added danger that
- exists along with the use of this medication.
- 15 Q. Okay. There are warnings and precautions in
- every FDA-approved label; is that correct?
- 17 A. Yes. The black box warning does go a little
- 18 bit further than that. It sets it apart and makes
- 19 sure that you see that first.
- Q. In fact, am I correct that the black box
- warning is meant to signal the most pressing of
- 22 warnings and draw extra attention to the prescriber
- about the concerns included within the black box; is
- 24 that correct?
- MR. CHALOS: Object to the form.

- 1 A. Yeah, I think that's consistent with what I
- described. I used different words but I think it's
- 3 consistent.
- Q. So let me ask it this way. Not all products
- 5 have black box warnings, correct?
- A. Yes, that's true.
- 7 Q. What -- what prompts a black box warning for
- 8 a product as opposed to one that doesn't have one?
- 9 MR. CHALOS: Object to the form.
- 10 A. Yeah, so I, you know, I've said many times
- I'm not an FDA expert so I can't tell you the exact
- 12 criteria that they use, but my understanding as a
- pharmacist about when a drug gets a black box
- warning is when we have what are called
- postmarketing surveillance data, or something we've
- learned about the drug since it's been on the market
- that needs to be included in the labeling that
- 18 warrants special attention.
- 19 Q. Okay. And will you agree with me that the
- 20 purpose of the black box warning is to convey to the
- 21 prescriber that there are particular heightened
- risks associated with the product bearing the black
- 23 box warning?
- MR. CHALOS: Object to the form.
- 25 A. I think we're saying the same thing, yes.

- 1 Q. Okay. Just wanted to make sure.
- Would you mind reading to me the first
- 3 paragraph within the black box warning?
- 4 A. Yes, and I will read it slowly.
- 5 Q. Sorry.
- 6 A. "Duragesic contains a high concentration of
- 7 a potent Schedule II opioid agonist, fentanyl.
- 8 Schedule II opioid substances which include
- 9 fentanyl, hydromorphone, methadone, morphine,
- 10 oxycodone, and oxymorphone have the highest
- 11 potential for abuse and associated risk of fatal
- overdose due to respiratory depression. Fentanyl
- can be abused and is subject to criminal diversion.
- 14 The high content of fentanyl in the patches
- 15 (Duragesic) may be a particular target for abuse and
- 16 diversion."
- 17 Q. Thank you, Doctor. If we flip over to
- Page 2, we're still in the black box warning,
- 19 correct?
- 20 A. Yes.
- Q. If you look down into the fourth paragraph,
- 22 am I correct that it reads: "Duragesic can be
- abused in a manner similar to other opioid agonists,
- legal or illicit. The risk should be considered
- when administering, prescribing or dispensing

- 1 Duragesic in situations where the health care
- 2 professional is concerned about increased risk of
- 3 misuse, abuse or diversion."
- 4 Did I read that correctly?
- 5 A. Yes.
- 6 Q. Okay. And that is within the black box
- 7 warning of this 2003-2005 period label?
- 8 A. Yes.
- 9 Q. I'm going to attempt to help the court
- 10 reporter. I don't know if that helps or not.
- And then the next paragraph down, midway
- into it, this is the paragraph that begins:
- "Persons at increased risk for opioid abuse
- 14 include..."
- And then the next sentence says: "Patients
- 16 should be assessed for their clinical risks for
- opioid abuse or addiction prior to being prescribed
- opioids. All patients receiving opioids should be
- 19 routinely monitored for signs of misuse, abuse and
- 20 addiction."
- Is that correct?
- 22 A. Yes.
- Q. Okay. I'm now going to flip ahead in this
- to Page 11. Happily we now have page numbers so it
- should be easier to find. And in this section you

- will see there is a section towards the bottom of
- the page, "Misuse, Abuse and Diversion of Opioids,"
- 3 correct?
- 4 A. Yes.
- 5 Q. And again, this section discusses that:
- 6 "Fentanyl is an opioid agonist of the morphine-type.
- 7 Such drugs are sought by drug abusers and people
- 8 with addiction disorders and are subject to criminal
- 9 diversion."
- 10 Did I read that correctly?
- 11 A. You did.
- 12 Q. And the next paragraph is: "Fentanyl can be
- abused in a manner similar to other opioids, legal
- or illicit."
- And is actually -- it goes on, it's a
- 16 similar -- the similar warning to what we just read
- in the black box section, correct?
- 18 A. It is, yes.
- 19 Q. Okay. And if we page ahead, I think we can
- set this -- okay. Let's set this one aside, as fun
- 21 as it is reading labels.
- You can put that aside, Dr. Perri.
- 23 (Perri Exhibit 15 was marked for
- identification.)
- 25 BY MR. GALIN:

- 1 Q. I will now show you what has been marked
- 2 Exhibit 15.
- MR. GALIN: Oops. I'm trying to balance the
- 4 getting it to you without being aggressive.
- 5 BY MR. GALIN:
- Q. All right. Do you recognize this document,
- 7 Dr. Perri?
- 8 A. I believe so, yes. I know what it is, yes.
- 9 Q. Okay. This is the current -- I will
- 10 represent to you this is the current Duragesic
- 11 package insert, and if you flip to the very last
- page you will see it's dated 2009, so it's the label
- that's been in effect since 2009.
- 14 A. Right.
- Q. Do you agree with me that that's what this
- 16 is?
- 17 A. I believe that to be the case, yes.
- 18 Q. Okay. Again, I'll have you look, if you
- would, at the first page of this, and again am I
- 20 correct that there is a black box warning?
- 21 A. There is.
- Q. And would you read for me the first portions
- or the title of the black box warning?
- A. "Warning: Addiction, abuse and misuse;"
- Q. I'll let you stop. I won't make you read

- the whole thing, unless you feel it necessary.
- 2 A. No.
- Q. But that's -- okay. So the start of this
- 4 black box warning calls out addiction, abuse and
- 5 misuse risk; is that correct?
- 6 A. It does.
- 7 Q. Okay. And then if we go down the first --
- 8 there are bullets under the header for this black
- 9 box warning, correct?
- 10 A. There are.
- 11 Q. And the first bullet, would you mind -- I
- 12 hate to keep making you read, but read in the first
- bullet into the record for me, please.
- 14 A. "Duragesic exposes users to risks of
- addiction, abuse and misuse, which can lead to
- overdose and death. Assess patient's risk before
- 17 prescribing, and monitor regularly for these
- 18 behaviors or conditions."
- 19 Q. Okay. And can I trouble you to read to
- second one for me?
- 21 A. "To ensure that the benefits of opioid
- 22 analgesics outweigh the risks of addiction, abuse
- and misuse, the Food and Drug Administration (FDA)
- has required a Risk Evaluation and Mitigation
- 25 Strategy (REMS) for these products."

- Q. Okay. And then to give you a break, I'll
- take over. On the fifth bullet down, it reads:
- 3 "Prolonged use of Duragesic during pregnancy can
- 4 result in neonatal opioid withdrawal syndrome which
- 5 may be life-threatening if not recognized and
- 6 treated."
- 7 Did I read that correctly?
- 8 A. Yes.
- 9 Q. Okay. Can I ask you to page ahead to
- 10 Page 13, which is Section 5 of the label? Are we
- 11 there?
- 12 A. Yes.
- Q. Great. Would you mind reading the title of
- 14 Section 5.1 to me under the warnings and precautions
- 15 section?
- 16 A. "Addiction, Abuse, and Misuse."
- 17 Q. Okay. And could I trouble you to read that
- 18 first paragraph?
- 19 A. "Duragesic contains fentanyl, an opioid
- 20 agonist and a Schedule II controlled substance. As
- 21 an opioid, Duragesic exposes users to the risks of
- 22 addiction, abuse, and misuse. Because
- 23 modified-release products such as Duragesic deliver
- the opioid over an extended period of time, there is
- a greater risk for overdose and death due to the

- larger amount of fentanyl present."
- Q. Thank you. And then the second paragraph
- reads: "Although the risk of addiction in any
- 4 individual is unknown, it can occur in patients
- 5 appropriately prescribed Duragesic. Addiction can
- occur at recommended doses and if the drug is
- 7 misused or abused."
- 8 Did I read that correctly?
- 9 A. Yes.
- 10 Q. And then the next paragraph reads: "Assess
- 11 each patient's risk for opioid addiction, abuse, or
- misuse prior to prescribing Duragesic, and monitor
- all patients receiving Duragesic for the development
- of these behaviors and conditions. Risks are
- increased in patients with a personal or family
- 16 history of substance abuse (including drug or
- 17 alcohol abuse or addiction) or mental illness (e.g.,
- major depression)."
- 19 Did I read that correctly?
- 20 A. I think so.
- Q. All right. 5.1 continues on the next page
- 22 and mentions that: "Opioids are sought by drug
- abusers and people with addiction disorders and are
- 24 subject to criminal diversion. Consider these risks
- when prescribing or dispensing Duragesic."

- 1 Do you see that?
- 2 A. Yes.
- Q. And Section 5.2 discusses opioid analgesic
- 4 Risk Evaluation and Mitigation Strategy, REMS.
- Dr. Perri, what is a REMS?
- A. It's exactly what the name suggests. It's a
- 7 way to -- it's a mandated program that's designed to
- 8 help enure that drug use will be appropriate by
- 9 implementing a few steps, for example, having people
- who prescribe a drug with a REMS complete an
- 11 educational program related to that product or the
- 12 REMS program itself, it includes information to be
- passed out. It includes warnings and precautions
- and other information that prescribers would need to
- know, pharmacists would need to know in order to
- make sure the patient was prescribed and monitored
- 17 properly.
- 18 Q. Am I correct that the purpose of a REMS in
- 19 this situation is to ensure that patient -- or
- 20 excuse me, that physicians are well educated on the
- risks associated with using this product?
- MR. CHALOS: Object to the form. It's
- outside the scope of his opinions here.
- A. The -- to the extent that the -- that most
- of the REMS that I'm familiar with require some type

- of education program, I guess that would -- that
- would mean that your statement is true. I haven't
- evaluated that or I'm not an expert on REMS programs
- 4 to tell you that they are effective or not
- 5 effective, but I think certainly the intent of the
- 6 REMS, as I understand it as a pharmacist, even
- 7 though it's not really related to what I did here,
- 8 was to make sure that the information that needed to
- 9 be out in the marketplace about a particular drug
- would be there, and precautions were in place.
- 11 Q. You've said, and your lawyer objected that
- it's outside the scope of what you've done here, you
- said you didn't review it, but you did in fact cite
- 14 to the REMS documents and training materials in your
- 15 report, did you not?
- 16 A. Yes, I referenced the REMS programs and I'm
- 17 generally familiar with them, but I don't -- I did
- 18 not evaluate whether any of them were effective at
- 19 accomplishing their goals or not.
- 20 Q. Okay. Right. But you reviewed the REMS as
- 21 part of your review and included it in your report?
- 22 A. I did -- I did read the various documents
- associated with some of the REMS programs. I'm sure
- I haven't seen all of them over every instance in
- time, but I've seen many of them, yes.

- 1 Q. Fair enough. Okay. Could I ask you to page
- ahead to page 33?
- 3 A. Okay.
- 4 Q. Do you see Section 9?
- 5 A. Yes.
- 6 Q. What is the title of Section 9?
- 7 A. "Drug Abuse and Dependence."
- Q. Okay. And Section 9.2 is titled "Abuse."
- 9 Am I correct?
- 10 A. Yes.
- Q. Within Section 9.2, one of the -- the final
- 12 sentence is: "Duragesic can be abused and is
- subject to misuse, addiction, and criminal
- 14 diversion."
- 15 Citing back to the warning we read before in
- 16 Section 5.1; am I correct?
- 17 A. Yes.
- 18 Q. Okay. The next paragraph says that: "The
- 19 high drug content in long-acting formulations adds
- to the risk of adverse outcomes from abuse and
- 21 misuse."
- 22 Is that correct?
- 23 A. Yes.
- Q. And the next paragraph: "All patients
- treated with opioids require careful monitoring for

- signs of abuse and addiction, because use of opioid
- 2 analgesic products carries the risk of addiction
- 3 even under appropriate medical use."
- 4 Did I read that correctly?
- 5 A. Yes.
- 6 Q. Okay. Set that aside for the moment.
- 7 Hopefully for good.
- 8 So the good news, Dr. Perri, is we've gone
- 9 through all the labels I want to show you for
- 10 Duragesic. The bad news is we have a second product
- in this case. So now we're going to do a similar
- exercise, if you will bear with me, for Nucynta.
- 13 Again, I'm going to show you what's been previously
- marked Exhibit 16.
- 15 (Perri Exhibit 16 was marked for
- 16 identification?)
- 17 BY MR. GALIN:
- 18 Q. Do you recognize this document, Doctor?
- 19 A. Yes.
- Q. What do you recognize this document to be?
- 21 A. It's to be -- appears to be the prescribing
- 22 information for Nucynta.
- Q. Indeed this is the 2008 Nucynta package
- insert or product label, depending on the
- terminology you want to use.

- 1 A. Yes, it is.
- Q. And if you look at the very -- there are two
- 3 columns on the front page. If you look at the top
- 4 right, there is a bullet. Could you read that
- 5 bullet for me?
- 6 A. "Abuse potential may occur. Monitor
- 7 patients closely for signs of abuse and addiction."
- 8 Q. Okay. And if we were to go to -- that
- 9 references parenthetically 5.4, which is Section 5.4
- of the label. So if we turn to Page 5, which has
- 11 Section 5.4 on it --
- 12 A. Yes.
- MR. CHALOS: Let me just interpose an
- objection. My copy says "Tradename TM" on it.
- Is that -- am I looking at the right document?
- MR. GALIN: Yes.
- 17 MR. CHALOS: Okay. How do we know this is
- 18 Nucynta?
- MR. GALIN: I will represent to you that
- it's Nucynta and that is the -- it isn't -- the
- words used on here is the clinical name rather
- than the marketing name.
- 23 MR. CHALOS: This is the final version of
- 24 the label?
- MR. GALIN: Of the 2008 version, yes.

```
MR. CHALOS: Okay.
 1
 2.
             MR. GALIN: As you may guess, we'll get to
 3
         look at some subsequent in a moment.
 4
              MR. CHALOS: So we'll accept your
 5
         representation. I don't know if that's true or
 6
        not but just -- I -- let me interpose an
 7
         objection subject to your questions that, you
 8
        know, we trust you, we believe you are telling us
 9
        the truth, but I just want to note that it
10
         doesn't say that on the document, so --
11
              MR. GALIN: Understood and appreciated and
12
        noted.
     BY MR. GALIN:
13
14
        Ο.
              So 5.4, just to throw your counsel even
15
      further off, uses the other clinical name,
16
     tapentadol, which is the more commonly understood
17
     name for Nucynta, says: "Tapentadol is a mu-opioid
18
      agonist. Such drugs are sought by drug abusers and
19
     people with addition disorders."
20
              Is that correct, what I wrote --
21
             Do pronunciations count?
        Α.
22
            Yeah. Mu.
        Q.
23
        A. Yes. Thank you.
             Fair enough. Yes, my apologies for that.
24
        Q.
25
              It goes on to say that: "Tradename can be
```

- abused in a manner similar to other opioid agonists,
- legal or illicit. This should be considered when
- 3 prescribing or dispensing Tradename in situations
- 4 where the physician or pharmacist is concerned about
- 5 an increased risk of misuse and abuse."
- Again, as your lawyer pointed out, Tradename
- 7 was the placeholder. This is the final version with
- 8 Nucynta put it in and you saw Tapentadol.
- 9 Did I read that correctly?
- 10 A. Yes.
- 11 Q. Okay. It goes on to say that: "Tapentadol
- may be abused by crushing, chewing, snorting or
- injecting the product. These practices pose a
- 14 significant risk to the abuser that could result in
- overdose and death."
- 16 And it cites to Section 9. Is that correct?
- 17 A. Yes.
- 18 Q. And if we were to head up to Section 9,
- which is on Page 12, Drug Abuse and Dependence, 9.1,
- 20 Controlled Substance, discusses that: "This product
- 21 has an abuse potential similar to hydromorphone, can
- 22 be abused and is subject to criminal diversion."
- Do you see that at the very bottom of
- 24 Page 12?
- 25 A. I do.

- Q. Okay. And I won't subject us all to all of
- the reading of 9.2 on Page 13, but that's entitled
- 3 "Abuse," correct?
- 4 A. Correct.
- 5 Q. And discusses addiction as a primary chronic
- 6 neurobiological disease with genetic, psychosocial
- 7 and environmental factors influencing its
- 8 development and manifestations, correct?
- 9 A. Yes.
- 10 Q. Okay. And if you turn the page, 9.3
- 11 discusses dependence, correct?
- 12 A. Yes.
- Q. Okay. Let's set this one aside. I promise
- 14 you we are getting closer. I'm going to show you
- what has been premarked 17.
- 16 (Perri Exhibit 17 was marked for
- 17 identification.)
- 18 BY MR. GALIN:
- 19 Q. Do you recognize this document?
- 20 A. This appears to be the 2011 version of the
- Nucynta extended release package insert or
- 22 prescribing information.
- Q. Okay. And am I correct that if you look on
- the top left of this, this is the 2011, it says
- 25 "Initial US Approval: 2011"?

- 1 A. Yes.
- Q. And if you look on the final page of this
- document, it confirms this is the 2011 version?
- 4 A. Yes.
- 5 Q. And am I correct that just below that on the
- front page is yet another black box warning?
- 7 A. It is.
- 8 Q. Okay. And will you read the first line
- 9 underneath -- within the black box warning?
- 10 A. "Potential for abuse, proper patient
- 11 selection and limitations of use."
- The first word was "Warning." I'm sorry.
- 13 Q. Thank you. And then if you could read the
- 14 bolded material just below "See full prescribing
- 15 information."
- 16 A. "Nucynta ER contains that tapentadol, a
- mu-opioid agonist and Schedule II controlled
- substance, with risk of misuse, abuse, and
- diversion, similar to other opioid analgesics."
- Q. Thank you. Can we page ahead to Page 8,
- 21 Section 5.5. I will say on Page 7 you will see
- 22 Section 5 is entitled "Warnings and Precautions,"
- and on Page 8, Section 5.5 is entitled "Misuse and
- 24 Abuse." Correct?
- 25 A. Yes.

- 1 Q. Similar language to what we just read about
- 2 tapentadol being "a mu-opioid agonist and is a
- 3 Schedule II controlled substance. Such drugs are
- 4 sought by drug abusers and people with addiction
- 5 disorders." Correct?
- 6 A. Yes.
- 7 Q. And then if we go down two paragraphs, there
- is a paragraph that says: "Nucynta ER can be abused
- 9 in a manner similar to other opioid agonists, legal
- or illicit. This should be considered when
- 11 prescribing or dispensing Nucynta ER in situations
- where the physician or pharmacist is concerned about
- an increased risk of misuse and abuse."
- 14 Am I -- did I read that correctly?
- 15 A. I think so, yes.
- 16 Q. And if we flip to the next page, the top of
- 17 Page 9: "Drug abusers may attempt to abuse Nucynta
- 18 ER by crushing, chewing, snorting or injecting the
- 19 product. These practices may result in the
- 20 uncontrolled delivery of Nucynta ER and pose a
- significant risk to the abuser that could result in
- 22 overdose and death."
- Did I read that correctly?
- 24 A. Yes.
- Q. Okay. And if we were to page ahead to

- 1 Page 18 here in Section 9 of the label or package
- insert, and this is entitled "Drug Abuse and
- 3 Dependence, " correct?
- 4 A. Yes.
- 5 Q. In the second paragraph, under 9.2, is --
- the section entitled "Abuse," the second paragraph
- 7 reads: "The risks of misuse and abuse should be
- 8 considered when prescribing or dispensing Nucynta
- 9 ER."
- 10 Correct?
- 11 A. Yes.
- 12 Q. Okay. You can set this one aside. Good
- news, the final of these labels, which has been
- 14 premarked 18.
- 15 (Perri Exhibit 18 was marked for
- 16 identification.)
- 17 BY MR. GALIN:
- 18 Q. Do you recognize this, Dr. Perri?
- 19 A. This is also Nucynta ER from 2008.
- 20 Q. Okay. '18, I believe. 2018, Is that what
- 21 you said?
- A. No, this one is 2008, I believe. Well, no,
- that's the initial approval date, so let's see.
- Q. If you look in the bottom right-hand corner,
- where it says "Revised" on the front page.

- 1 A. Yes, 2018. Generally, the very last line --
- yes, there it is, September 2018.
- Q. And again, this has a black box on the front
- 4 left?
- 5 A. It does.
- Q. And it again starts with: "Warning:
- 7 Addiction, abuse, and misuse."
- 8 Correct?
- 9 A. Yes.
- 10 Q. Okay. And this contains a similar
- 11 discussion of the risks associated with addiction,
- abuse, and misuse, and the use during pregnancy that
- we've read in the previous labels. Am I correct?
- 14 A. Yes.
- Q. Okay. We can happily read them, but I think
- people will prefer we don't, so we'll skip ahead to
- 5.1. Section 5.1 is "Warnings and Precautions,"
- 18 correct?
- 19 A. Yes, Section 5 is "Warnings and
- 20 Precautions."
- Q. Yes. And 5.1 is "Addiction, Abuse, and
- 22 Misuse"?
- 23 A. Yes.
- Q. And I will just read. The first paragraph
- under 5.1 reads: Nucynta ER contains tapentadol, a

- 1 Section II controlled substance. As an opioid,
- 2 Nucynta ER exposes users to the risks of addiction,
- abuse, and misuse. Because extended-release
- 4 products such as Nucynta ER deliver the opioid over
- 5 an extended period of time, there is a greater risk
- for overdose and death due to the larger amount of
- 7 tapentadol present."
- 8 Did I read that correctly?
- 9 A. I think you said Section II controlled
- 10 substances, instead of Schedule II. I may have
- 11 misheard you, though.
- 12 Q. I probably misspoke but if I did, I
- appreciate you correcting it. It's a Schedule II
- 14 controlled substance.
- And then the next paragraph: "Although the
- risk of addiction in any individual is unknown and
- can occur in patients appropriately prescribed
- Nucynta ER, addiction can occur at recommended doses
- and if the drug is misused or abused."
- The next paragraph goes on to direct the
- 21 physician to: "Assess each patient's risk for
- opioid addiction, abuse, or misuse prior to
- prescribing Nucynta ER, and monitor all patients
- receiving Nucynta ER for the development of these
- 25 behaviors and conditions."

- 1 Have I read all that correctly?
- 2 A. Yes.
- Q. Okay. And Section 9, again, is "Drug Abuse
- 4 and Dependence." Do you see that?
- 5 A. Yes.
- Q. And again, 9.2 is "Abuse" and contains
- 7 lengthy warnings and directions to the physician
- 8 regarding the potential for abuse of this product;
- 9 is that correct?
- 10 A. Yes.
- 11 Q. Okay. You can set that aside.
- Doctor and, frankly, everyone, I appreciate
- your patience with me as we went through that
- exercise, but I think it's an important one.
- Did you review the -- these labels or
- 16 product inserts as part of your effort in this
- 17 matter?
- 18 A. Yes. I made -- to the best I could, I made
- a specific effort to make sure I'd seen the PIs for
- all of the drugs.
- Q. Do you agree with me that after that lengthy
- 22 exercise, there is significant and extensive
- 23 warnings regarding addiction, abuse, misuse, abuse,
- and dependence issues in each version of the
- Duragesic, Nucynta and Nucynta ER labels?

- 1 MR. CHALOS: Object to the form.
- 2 A. So based on what we've seen, I would agree
- with you that there is plenty of warning information
- 4 in the PI. The only thing I would say about that is
- 5 I think I've expressed my opinions about the utility
- of the PI in the overall mix of the marketing
- 7 materials, but yes, I agree that there are warnings
- 8 contained in all of the PIs that we just reviewed.
- 9 Q. Okay. And just so that -- because your
- lawyer objected, I will go with am I correct that
- 11 there is -- that warning information is in each of
- the Duragesic labels?
- MR. CHALOS: Same objection.
- 14 A. Yes. The ones we just reviewed, the
- warnings, different -- over time the warnings
- change, but the warnings were present in all of the
- 17 PIs that we looked at.
- 18 Q. And that includes Nucynta as well?
- 19 A. Yes.
- Q. And Nucynta ER?
- 21 A. Yes.
- Q. Okay. Doctor, you said that you believed
- the product inserts have limited utility, correct?
- A. They are a piece of the puzzle, but they are
- not the only piece, so their utility has to be

- 1 considered with respect to that, and as we read
- through them, they're fairly long and very detailed
- in some cases, so their utility for physicians is
- 4 limited by that.
- 5 But I think the main thing that -- the main
- opinion that I've expressed is that the PI is just
- one piece of the marketing that was presented, and
- 8 certainly these are all good examples that they
- 9 provide warnings.
- 10 Q. Okay. And in fact -- we will come back to
- 11 that, but one of the things you mentioned is --
- 12 yesterday, I can't remember who was speaking with
- 13 you, it might have been Mr. Volney, that -- I think
- 14 you testified that any time the product name and
- indication are mentioned, I think you've used be it
- even on a muq, it has to be -- the product insert or
- 17 label, package insert, product label, must be
- provided; is that correct?
- 19 A. Yes, and it was in reference to my
- understanding of when they had to provide a PI,
- which was any time they did those two actions
- together. And the mug example was an old-school
- reference, because, of course, we know they don't do
- that -- no one does that any more, but I remember,
- you know, years passed getting a coffee mug that

- would say Nucynta or whatever and there would be an
- annoying package insert folded up very tightly stuck
- 3 to the side of it. So...
- Q. Okay. And am I correct that in your review
- of -- well, let me --
- In your review of the documents for Janssen,
- 7 for this exercise, did you gain an understanding of
- 8 whether Janssen's sales representatives were
- 9 required to provide the package insert when engaging
- in what I believe you referred to as personal
- 11 selling?
- 12 A. Depending on the nature of their visit, my
- answer would be yes, but I think that -- I don't see
- evidence that the package inserts were distributed
- inappropriately at any point.
- Q. And when you say distributed
- inappropriately, the only inappropriate would mean
- if they weren't distributed, correct?
- 19 A. Right. I think that's something that
- industry people pay a lot of attention to because
- it's a well-understood requirement and I think
- 22 everyone wants to be as diligent as possible making
- sure the package insert is presented when it needs
- 24 to be.
- Q. So as you sit here today you have no reason

- to believe that sales reps for Janssen did not
- distribute the package insert whenever discussing
- 3 the product and its indications, correct?
- 4 MR. CHALOS: Object to the form.
- 5 A. That's -- I -- yes, I agree that I haven't
- 6 seen any evidence that they didn't do that. I still
- 7 have to say, though, I question the utility of it
- 8 given the big picture of the marketing, but I
- 9 certainly agree with that statement.
- 10 Q. So let me talk about the question about the
- 11 utility. Why is it that you question the utility of
- the package insert?
- 13 A. Well, I think we've established through
- 14 these last two days that, you know, physicians are
- busy folks and they need information. They also
- 16 need information that is succinct and relevant to
- the decision they are making at that moment in time.
- The package insert, as we've just gone
- through, these are extensive documents and they are
- 20 generally not in this nice of a fashion to read.
- 21 They are generally a big sheet with print so small
- you can't even really read them. But the main point
- is, is that they are one piece of a much larger
- 24 program of marketing that is presented related to
- 25 all of these products, Nucynta and Duragesic

included, that focuses on product features and 1 2. product benefits, the things that are most at the 3 front of physicians' minds when they are trying to 4 make a decision about what their patient needs, and 5 what might be the best choice for their patient. 6 And certainly those bigger -- the bigger 7 more fuller scope focuses on the well-crafted and 8 well-defined, well-thought-out, well-planned 9 strategies that defendants have figured out will be the most effective at increasing sales of these 10 11 products. 12 So for that reason, given the busy nature of 13 the physician, given the presentation of the 14 material in the PI not being the most user friendly 15 in many cases, and the large volume of other 16 marketing materials, and that includes the CE 17 programs and the use of key opinion leaders and all 18 the different ways that manufacturers reach out to 19 physicians to educate them about their drugs, the 20 package insert plays a role but it's a smaller role than most of the other types of marketing just in 21 terms of how much utility it has during that patient 22 23 encounter for a decision-making. You've mentioned a couple of times the large 24

and dense nature, so to speak, of the package

25

- insert. Am I correct that one of the ways meant to
- address the depth and breadth of it is to provide
- 3 the black box warning up front, that in a succinct
- 4 way, as you put it, directs the physicians to that
- 5 warning information?
- 6 MR. CHALOS: Object to the form.
- 7 A. Yeah, that's -- that's true.
- 8 Q. And in fact, as we looked at, with one
- 9 exception, which was the first Duragesic label,
- 10 every one of the labels we looked at had a black box
- warning that covered addiction, abuse, and misuse;
- is that correct?
- 13 A. That statement is correct, yes.
- Q. Okay. And in fact, in that one Duragesic
- label that we looked at, and you have it, it's
- 16 Exhibit 13 if you would like to go back, I think I
- 17 asked you to read the very first thing under the
- name on the top of the label and I believe you read
- a warning about abuse risk; is that correct?
- A. As I recall, yes, that's correct.
- Q. Okay. You -- do you know whether or not
- 22 physicians are trained or taught either in medical
- 23 school or otherwise the importance of reviewing and
- 24 understanding package inserts?
- 25 A. I don't know specifically what their

- 1 training involves. My understanding about what
- 2 physicians get in medical school in terms of
- 3 pharmacology training is that it's very minimal and
- 4 that most of their drug knowledge comes from their
- 5 practice experience on medical school campuses,
- 6 where they first begin seeing patients and
- 7 prescribing medications.
- And from a marketing perspective, we also
- 9 know that marketers tend to spend a lot of time in
- 10 those environments, to be there present during a
- 11 physician's early training years. So that's my --
- that's about the extent of my knowledge about what
- they get in terms of training. I don't know that
- 14 they're -- or that they are or are not trained on
- 15 how to interpret a package insert.
- Q. Well, do you think that doctors understand
- the importance of a package insert?
- 18 A. I think over time that perhaps has been --
- there would be a different answer to that question,
- 20 because I know back in the 1990s we didn't have
- 21 handheld pharmaceutical reference capabilities. Now
- certainly we do, and I don't know any doctor that
- refers to the PDR ever anymore, but I do -- and in
- fact, they stopped making the PDR at some point in
- 25 the mid 2000s.

```
1
              The PDR was a collection of package inserts,
      and so at least during the time period that the PDR
 2.
 3
      was around there would have been more reliance on
 4
      that, but since that point in time, with the advent
 5
     of all the handheld and computer-based drug
      information systems, I think the importance of the
 6
 7
     package insert is greatly diminished.
 8
         Ο.
              The FDA still considers the package insert
      an important part of marketing and information -- a
10
      source of information for physicians, correct?
11
              MR. CHALOS: Object to the form.
              So the FDA's characterization of it, I don't
12
        Α.
13
     know what they call it, but I can tell you from my
14
     perspective what I look at the -- the PI is what
15
      sets the boundaries around which a pharmaceutical
16
     manufacturer who wants to market their product can
17
      engage, and the package insert outlines that, I
18
      think, in a lot of detail. The black box warning is
      required, the indications, all of that are laid out.
19
20
              So within the scope of the package insert as
     your boundaries, those are the things that can be
21
22
      discussed, so it's an important part of the
23
     marketing, I agree. I don't know what the FDA
24
      thinks but to me it's an important part of
25
     marketing.
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- 1 Q. Are you familiar with the term Important
- 2 Safety Information or ISI?
- 3 A. Yes.
- 4 O. What is ISI?
- 5 A. The information that's usually contained in
- 6 the package or prescribing information relative to
- 7 safe use of the product.
- Q. And am I correct that pharmaceutical
- 9 manufacturers are required to include the ISI within
- 10 their -- in a fair and balanced way on their
- 11 marketing pieces?
- 12 A. Yes, that's my understanding.
- 13 Q. Okay. And in your review of Janssen's
- documents, have you seen any indication that it ever
- failed to include the ISI in its marketing pieces?
- 16 A. I don't recall anything specific where they
- 17 did not include the important safety information --
- 18 Q. Okay.
- 19 A. -- in a marketing piece.
- 20 Q. To the extent that the product insert is
- given to -- or the package insert is given to
- 22 physicians, as you've said it's your understanding
- it is, is it the manufacturer's fault that it is not
- read or it is not considered by the physician, if in
- 25 fact that's the case?

I mean, I hate to use the word fault, 1 Α. Gosh. but what comes to my mind about that is, is that, 2. 3 you know, the manufacturer has a lot of options when they decide what information to present, and I think 5 my opinion is, is that the package insert generally 6 is a boundary and I think most people respect that 7 boundary, most manufacturers do. 8 The problem arises in what information is 9 focused on. It's one thing to bring lunch to a 10 doctor's office and leave a package insert. It's 11 another thing to meet personally with that doctor 12 and to discuss the talking points that are designed, 13 mapped out weeks ahead of time, strategized a year 14 ahead of time by a marketing planner, and expect the 15 doctor to pay more attention to the package insert 16 than the personal communication. 17 So is it -- is it their fault? I mean, 18 essentially, it's designed so that the information 19 that's remembered by the doctor is the information 20 that will promote the product, not restrict its use, so in -- at the end of the day, the marketing pieces 21 22 that are designed to focus on product features and 23 the benefits that those bring to patients and doctors who use them. 24

The reasons why this drug is better than the

25

- 1 competition, the reasons why this drug works better
- than other therapies, those are all the messages
- 3 that get recalled.
- So at the end of the day, I quess I don't
- 5 like to use the word their fault, but I guess in a
- 6 marketing sense, it's because of their actions that
- 7 those are the things that are remembered and that
- 8 the PI is not relied on.
- 9 Q. In a number of the documents you looked at,
- am I correct that they said "cannot be left behind"?
- 11 A. There were documents that did say "this is
- not a leave behind," "do not share with customers."
- I can't recall a specific one right now to point you
- 14 to, but the -- I know that on many of the documents
- 15 I saw in the data -- in the document production,
- 16 there would be designations about whether a document
- is permissible to be left behind or not, or if it
- was intended to be left behind, "this is approved
- 19 for distribution."
- Q. And yet, as you said, the package insert is
- 21 always left behind, correct?
- MR. CHALOS: Object to the form.
- 23 A. The package insert is left behind when it
- 24 meets those criteria for why it needs to be left
- behind. So if the -- if you're talking about

- 1 Nucynta and its indications, then you would need to
- 2 leave a package insert.
- Q. So we -- if something is going to stay
- 4 behind, it will be the package insert in those cases
- with the black box warning on it, correct?
- 6 MR. CHALOS: Object to the form.
- 7 A. Yeah, depending on the circumstance. If it
- 8 was a -- if they meet the criteria for needing to
- 9 leave a package insert, I'm sure they probably would
- 10 have.
- 11 Q. Okay. Are --
- THE WITNESS: How long have we been going?
- MR. CHALOS: Over an hour.
- MR. GALIN: Do you want to take a --
- 15 THE WITNESS: I kind of need to take a short
- 16 break.
- 17 MR. GALIN: Certainly. Absolutely.
- 18 THE WITNESS: Thank you.
- THE VIDEOGRAPHER: We are now going off the
- video record. The time is currently 11:28 a.m.
- This is the end of the Media Number 2.
- 22 (Recess from 11:28 a.m. until 11:40?a.m.)
- THE VIDEOGRAPHER: We are now back on the
- video record with the beginning of Media
- Number 3. The time is currently 11:40 a.m.

- 1 MR. GALIN: Thank you.
- 2 BY MR. GALIN:
- Q. Dr. Perri, before the break, one of the
- 4 things you were mentioning was that time is spent
- 5 preplanning the way pharmaceutical manufacturers
- 6 will discuss product features and attributes during
- 7 personal selling in advance of those sales calls,
- 8 correct?
- 9 A. Yes.
- 10 Q. Okay. During the break I placed before you
- what's been marked as Exhibit 19 and I've shared
- 12 with your counsel.
- 13 (Perri Exhibit 19 was marked for
- 14 identification.)
- 15 BY MR. GALIN:
- 16 Q. You may recognize this. I know you looked
- 17 at a lot of documents, but you may recognize this as
- some -- a Janssen document Bates stamped JAN00085130
- 19 that is cited in your report at Page 75, Footnote
- 20 245. I won't blame you if you don't actually
- 21 remember this specific document.
- 22 A. Actually, I do.
- Q. Oh, great. I really -- you don't -- you're
- obviously entitled to look through all of it, but I
- will tell you I really only want to ask you a

- 1 question about what is the first substantive slide
- on Page 2 of this printout deck. Do you see that
- 3 slide?
- 4 A. I do.
- Q. And the title is "Compliance is Essential,"
- 6 correct?
- 7 A. It is.
- Q. Am I correct that the first bullet reads:
- 9 "As a sales representative, it is my responsibility
- 10 to" and then a colon?
- 11 A. Yes.
- 12 Q. Okay. The first bullet under the colon,
- 13 could you read that for me?
- 14 A. "Always promote the benefit and safety of
- our products consistent with the FDA-approved
- indications and prescribing information."
- 17 Q. And the second.
- 18 A. "Disclose safety information for all
- 19 company-promoted products."
- Q. Okay. And if you look in the talking
- points, so to speak, the speaker notes that are
- underneath the print, there is one listed, "Slide
- 23 Objective."
- 24 A. Yes.
- Q. And it says: "Stress that compliance is

- 1 essential in everything we do when we are selling to
- our customers we must stay within the guidelines."
- Did I read that correctly?
- 4 A. Yes.
- 5 Q. Okay. So this document reflects, does it
- not, Dr. Perri, that Janssen took being compliant
- 7 and sharing safety information seriously, correct?
- 8 A. I think that's one of the things this
- 9 document definitely shows, yeah.
- 10 Q. Okay. You can set that aside. This is
- where I really get jumbled trying to sort of piece
- 12 stuff together, as I warned before, and to move this
- along, so bear with me for a second, but where I
- think I would like to go next is back to Table II of
- 15 your report and Page 89 in particular.
- So if I could ask you to -- this is
- 17 actually -- well, let's start on Page 88 of the
- 18 report, which is Letter B of Table II.
- 19 A. Okay.
- Q. Letter B on Page 88 is "Abuse deterrent
- 21 formulations deter abuse."
- 22 A. Yes.
- Q. And if you flip to Page 89, there is a
- Janssen entry that is the second entry on the page
- and it reads, and I quote -- quote you quoting from

- a document JAN-MS-00259893, quote: "only AP-48
- 2 combines the superior potency of fentanyl with
- naltrexone in a proprietary formulation to safeguard
- 4 against unintended usage."
- 5 Did I read that correctly? Do you see that?
- 6 A. Yes.
- 7 Q. Do you know what AP-48 is?
- 8 A. Off the top of my head, I don't recall, no.
- 9 Q. Okay. Do you know -- I will represent to
- 10 you that AP-48 is, as is suggested by the quote that
- 11 you have in the table, a developmental version of
- the fentanyl patch Duragesic meant to safeguard
- 13 against abuse.
- 14 A. Okay.
- 15 Q. Does that sound familiar? I take it you
- 16 don't know.
- 17 A. Yeah. I'm trying to remember the specific
- 18 document but --
- 19 Q. I could show it to you if you want --
- 20 A. No, that's --
- Q. -- but my question --
- 22 A. Tell me what your question is, yeah.
- Q. Well, my question is do you know if AP-48
- ever made it to market?
- A. I am not familiar with any fentanyl and

- 1 naltrexone combinations that made it to market.
- Q. In fact, I will represent that it did not.
- 3 A. Right.
- 4 Q. Okay. So considering that it did not make
- it to market, do you believe that this document from
- 6 which you quote was used in marketing?
- 7 MR. CHALOS: Object to the form.
- 8 A. So no, I don't believe this document was
- 9 used in the marketing; however, as I've mentioned in
- 10 prior questions like this, it shows the thought
- 11 process, what was going on internally within
- 12 defendants to look at abuse deterrent formulations
- and to bring abuse deterrents to the marketplace.
- 14 That was important to the marketing. There were a
- 15 number -- not a number, there were a few products
- that were developed, some got very far along, some
- 17 did not, but yet the processes that were engaged for
- those products were very similar to, if not
- identical to in terms of the plans and strategies,
- to products that didn't make it to market as the
- 21 ones who did.
- 22 So I did include -- and there are other
- 23 examples in this table of products that or messages
- that never made it to market because there was
- either a problem with the message or the product

- 1 never made it to market.
- Q. I guess what I'm struggling to understand
- 3 then, Dr. Perri, is if Table II, as I understand it
- 4 from your testimony, is meant to reflect examples or
- 5 the aggregate message that, as you said, has
- 6 influenced prescribers and led to this increased
- 7 growth, as you've stated, in opioid prescriptions,
- 8 why messages that were never actually used and why
- 9 messages about a product that never actually made it
- to the market would be included in your table?
- 11 A. I guess the best answer I can give you for
- that is, is that I wanted to be complete in my
- presentation of what the manufacturers planned and
- 14 executed, and just because something didn't make it
- to market didn't mean they didn't think about it.
- The abuse-deterrent concept was important.
- 17 It was important to more than just Janssen, and I
- think it was -- including that was one way of
- showing that there was an attempt made, there were
- 20 considerations given, to an abuse-deterrent
- formulation. It didn't work out, but yet it's
- important to note that from a -- the product
- development perspective, this was something that was
- on the radar because at this time -- and I shouldn't
- say at this time because I don't know when this

- document relates to specifically time-wise as I'm
- 2 sitting here right now, but over time manufacturers
- became more interested in abuse-deterrent
- 4 formulations because of a growing awareness
- 5 societally that we had a drug abuse problem in this
- 6 country, and that was one of the things that was
- 7 leading people to look at these abuse-deterrent
- 8 formulations.
- 9 Q. I guess what I'm struggling with again,
- 10 Dr. Perri, is there is nothing in your table, is
- 11 there, that distinguishes messages that made it to
- the public and to physicians and messages that never
- got outside the walls of the various defendants.
- 14 Correct?
- 15 A. The table summarizes messages that were in
- 16 the marketing materials. That's certain. The
- majority of the messages, as I recall, were from
- items that are certainly items that were distributed
- in the marketing materials. A few of the items in
- there, such as this one that you've pointed out
- 21 today, were -- and others, for example, MoxDuo, that
- 22 never made it to market. Another example I can give
- you from Endo that cites to the use -- or to
- 24 promoting the use for an incorrect indication, which
- was caught eventually, but it had other things in

- 1 that document that I was interested in making sure
- 2 made it to my table.
- 3 So there are a number of documents in there,
- 4 just a few, that never made it, but yet they reflect
- 5 thinking. And I can give you specifically with the
- 6 Endo document, for example, it references what I
- 7 considered to be a vulnerable population: Veterans.
- 8 And so regardless of whether it made it to market in
- 9 that form, it showed consideration of targeting
- veterans in the opioid marketing.
- So the requirements for ending up in this
- table were just that it was something that was in
- the marketing process within defendants' marketing.
- 14 It doesn't necessarily mean that they made it to
- market, although I'll represent that they did mostly
- 16 make it to market, and we can know for any one of
- 17 these whether it made it to market or not. That's
- not -- I mean, it's a possibility that that could be
- another column in the table, "Did it make it to
- 20 market or not." I just didn't do that at this
- 21 point.
- Q. Okay. I'll let my colleagues representing
- 23 Endo deal with the discussion about Endo for you.
- A. I'm sure they noticed that as well, so --
- Q. I suspect they probably did.

- I will skip ahead in the purpose of time, if
- you would, to I believe it is Page 104 of your
- report, and there are a number of -- actually,
- 4 excuse me. It's 103 that I want to look at. Oh,
- 5 actually, bear with me for one moment. All right.
- 6 Yes, it's 104. If you look under K, it
- 7 says: "Patients can be easily tapered off opioids."
- 8 Is that correct?
- 9 A. That's correct.
- 10 Q. And under K, the second document is a
- Janssen document that's referenced by its Bates
- number JAN00222151, correct?
- 13 A. Correct.
- Q. Would you read the -- for me the quote
- 15 there?
- 16 A. "Physical dependence is not the same as
- 17 addiction. It may be managed by gradually reducing
- 18 the dosage of the drug if the doctor decides it is
- 19 appropriate to discontinue therapy."
- Q. I don't see anything or didn't hear anything
- in there about it being easy, and yet this appears
- 22 under something that says "patients can be easily
- tapered off of opioids."
- Why is that?
- 25 A. We'd have to get the whole document to get a

- 1 sense of, you know, how it was being presented, but
- 2 I think certainly the sentiment that patients can be
- 3 tapered, and I think easily tapered, was something
- 4 that shows up in many documents, and, you know,
- 5 maybe the words that I've used to describe K aren't
- 6 perfect, but I don't think there would be any
- 7 argument that this phrase that's listed here,
- 8 "physical dependence is not the same as addiction,"
- 9 is making a statement. It's clearly saying just
- 10 because your patient is dependent, it doesn't mean
- 11 they're addicted. Okay? So that sort of sets the
- tone for it. And it may be managed by gradually
- reducing the dose, so here's the solution.
- This is indicative of just exactly how I saw
- the marketing messages being used by defendants.
- There's a problem, it's a barrier to opioid use.
- 17 I've identified these barriers in my report and
- there are categories, I think five barriers that
- 19 I've pointed out. One of them is this exact thing,
- that withdraw is a big concern.
- 21 And so the way that this is dealt with in
- the marketing documents is to minimize the concern
- and tell what the solution is. What does that do?
- 24 That promotes the use of opioids. That doesn't
- necessarily promote the appropriate use or the

- inappropriate use, and I did not make that judgment,
- but it promotes the use of opioids, which is why
- when looking at all of these documents and all of
- 4 the messages and all of the other marketing that
- went on, I was able to form the conclusion that the
- 6 marketing of the opioids, which focused on product
- 7 features and benefits, heavily focused on the
- 8 reasons why you should buy the product and not the
- 9 reasons why you shouldn't, led to the expansion of
- 10 the opioid market.
- 11 Q. Okay. I would, in a different time, go
- 12 through with you the discussion as to how -- the
- overall cite, but since it is -- the document to
- 14 which you cite is the Nucynta website -- or excuse
- me, the Duragesic website from 2006. It's hundreds
- upon hundreds of pages and I'll spare all of us that
- fun, but I do want to show you what I will mark
- 18 Exhibit 20, which is a printout from a different
- 19 website.
- 20 (Perri Exhibit 20 was marked for
- 21 identification.)
- 22 BY MR. GALIN:
- Q. This, if you look at the first page, you
- 24 will see that Pagevault captures the key facts as to
- 25 where this website comes from. This is the -- the

- 1 URL indicates that it's the FDA's website and the
- 2 section is for consumers and it's a consumer update
- 3 captured just this month on April 4th, 2019?
- 4 Do you see what I'm referring to?
- 5 A. I do.
- 6 Q. Okay. If you were to go to the second page
- of the printed version of the website, you will see
- 8 just past halfway down is a section -- and I
- 9 apologize for the small type, one of the problems
- 10 with a screen grab -- is "Misuse and Abuse." Do you
- 11 see the section I'm looking at?
- 12 A. Yes.
- Q. And its second paragraph reads under this --
- 14 well, for completeness or -- I'll read. The first
- paragraph is: "Misuse and abuse of pain medication
- 16 can be extremely dangerous. This is especially so
- in regard to opioids. These medications should be
- stored in a place where they cannot be stolen."
- 19 The second paragraph reads: "According to
- the National Institutes of Health, studies have
- shown that properly managed medical use of opioid
- 22 analgesic compounds (taken exactly as prescribed) is
- 23 safe, can manage pain effectively, and rarely causes
- 24 addiction."
- Did I read that correctly?

- 1 A. You did.
- Q. So will you agree with me that the FDA is
- 3 stating that when properly prescribed and man --
- 4 opioids can manage pain effectively and rarely cause
- 5 addiction?
- 6 MR. CHALOS: Object to the form.
- 7 A. That's what this says, yes.
- 9 Q. Okay. You can set that aside, Dr. Perri.
- 9 I'm mindful of the time and if my colleagues
- want to go. Let me sort of wrap up by going back to
- 11 something.
- When we started our discussion at least, one
- of the things you mentioned was that you have not
- 14 made any determinations as to whether or not any of
- the marketing claims that you've reviewed are false
- or misleading, correct?
- 17 A. I did not, that's correct.
- 18 Q. And in fact, you were relying on five other
- 19 experts and the FDA warning letters, I believe you
- said, correct?
- 21 A. Yes.
- Q. One of the things you've also said -- and
- just around that, you, when putting together your
- 24 report, were asked to assume, in fact, that the
- 25 marketing claims were false and misleading; is that

- 1 correct?
- 2 A. That's generally the way it was placed, yes.
- Q. Okay. And one of the things you said
- 4 earlier today when my colleague Mr. Carter was
- 5 speaking with you, and I think you said at least
- once, if not twice, yesterday is, in essence, that
- 7 -- the term used, "the crux of the matter" here, is
- 8 that the marketing of opioids has violated the
- 9 standards of marketing. I certainly don't want to
- tell you what you said, but do you recall something
- 11 along that effect?
- MR. CHALOS: Object to the form.
- 13 A. Yeah, I'm not sure I used those exact words
- but I think that's roughly a paraphrase of it.
- 15 Q. Let me use words that are yours from
- Paragraph 192 on Page 155 at the end of your -- the
- final presignature paragraph of your report?
- 18 A. Okay.
- 19 Q. You write: "Defendants violated marketing
- standards by creating and disseminating false or
- 21 misleading marketing messages that downplayed or
- 22 minimized the risks associated with opioids while
- emphasizing the benefits of their drugs, and by
- 24 disquising their support of activities aimed at
- increasing sales of their own products."

- 1 A. Yes.
- Q. If in fact it turns out that the assumptions
- 3 that you've been asked to make, that our marketing
- 4 was in some way false or misleading, turns out to be
- an incorrect assumption, does that not vitiate the
- 6 conclusions that you reach in your report?
- 7 MR. CHALOS: Object to the form; incomplete
- 8 hypothetical.
- 9 A. Let me read my sentence again and see how
- taking the word false or misleading out would impact
- the meaning of that sentence, and just give me one
- 12 second.
- 0. Of course.
- 14 A. So if I -- if I take out the words
- "disseminating false and misleading," it would just
- say "disseminating marketing messages that
- downplayed or minimized the risks associated with
- opioids while emphasizing the benefits of their
- drugs, and by disquising their support of activities
- aimed at increasing sales of their own products."
- I think the sentence remains true.
- Q. So if I'm understanding correctly, and I
- certainly don't want to put words in your mouth, but
- let me ask, am I correct in understanding that what
- you are telling me is that it's not necessary for

- our marketing, our being defendants' marketing, and
- I use us as a whole because you're talking about in
- the aggregate you haven't found anyone -- yes.
- 4 A. I'm sorry. The first part -- I focused on
- 5 the last part of the sentence. I didn't look at the
- 6 "violated marketing standards." That part of it I
- 7 have to think about. I haven't -- I just think that
- 8 the -- I guess what I was trying to say is that
- 9 the -- and I know that folks around this table are
- 10 probably tired of hearing me say that marketing
- works.
- 12 Q. Then we'll stop asking.
- 13 A. But the -- I think that the marketing,
- even -- whether the messages are false or
- misleading, that wasn't really relevant. The
- 16 marketing, what did it do, how did it do it, those
- opinions that I've expressed I think they remain
- 18 true.
- I need to think about this part, about did
- they violate marketing standards, that part I have
- 21 to think about, because I know for some of them
- there would still be a violation of the marketing
- standards. For example, the use of key opinion
- leaders where the relationship between the company
- and the KOLs was not disclosed, so in cases like

- 1 that.
- 2 So I would need to go through each and every
- 3 part of it and verify that each standard was or
- 4 wasn't violated. Does that provide you with an
- 5 answer you --
- Q. It provides me with your answer, which is
- 7 all I can ask for.
- 8 A. Okay.
- 9 Q. But what I'm really also trying to
- 10 understand here is you had said before, to your
- point, you've said a few times in this deposition
- that marketing is important and it worked, or that
- marketing works. I think in response to Mr. Carter
- earlier you said that marketing itself isn't
- 15 inappropriate.
- If I understand correctly, what you believe
- the defendants did inappropriately was violating the
- 18 standards of marketing, as you refer to in
- 19 Paragraph 192. Am I correct about that?
- MR. CHALOS: Object to the form.
- 21 A. The judgment about whether any particular
- message being appropriate or inappropriate wasn't
- 23 critical. The false and misleading, that does
- 24 relate to some of the standards. So false and
- 25 misleading, as -- when you asked me the question

- earlier, it does affect some of my judgment about
- the marketing, but taking that out, it would only
- 3 probably affect a few of the several standards that
- 4 are listed.
- If we took out some of the other words in
- 6 the sentence, it might also -- so it wasn't just
- 7 from the false and misleading perspective.
- And you're right, I didn't examine the
- nature of the ads, I relied on others to provide
- 10 that information.
- So I think we can break this down piece by
- 12 piece and get out each standard and look at just how
- it impacts that opinion, but I think the overall
- opinion is that some marketing standards were still
- violated even if we take out the false and
- 16 misleading nature that I relied upon in the
- 17 assumption to verify.
- 18 O. And which standards would those be?
- MR. CHALOS: Object to the form; incomplete
- 20 hypothetical.
- 21 A. If you look at Page 19, this is in the
- section on the standards that apply to
- pharmaceutical marketing, Paragraphs 34 through 36.
- 24 The -- assuming that what we're talking about is
- taking out the words "false and misleading" from

- 1 that statement, it -- again, I need to give this a
- lot more thought because I spent a lot of time
- 3 working on this report and a lot of time analyzing
- 4 documents, and just to jump into it here and give
- 5 you a quick opinion, I'm doing that because you've
- 6 asked the question, but I do like to think about
- 7 things.
- 8 Q. Okay. That's fair.
- 9 A. But it says that: "Marketing must always be
- 10 truthful. Marketing must never make false or
- 11 misleading statements to the medical community."
- So if we take those out the question would
- be do the -- do the FDA documents still give me
- pause and make me think that there is false and
- 15 misleading marketing?
- If we take away the FDA documents and the
- assumption of false and misleading, then I would
- 18 get -- I would probably formulate an even different
- opinion. So depending on the specific nature of the
- 20 hypothetical that we're talking about, I would yield
- 21 to you that if the ads were -- none of them were
- false or misleading, that I wouldn't say they
- violated the standard of not being truthful. It
- could still be, though, that the learning that would
- take place from those ads would violate some other

- standard, for example, not promoting the rational
- use of medication, promoting a use that goes beyond
- what we would call rational or appropriate use of
- 4 medicines.
- 5 So I would have to analyze it very carefully
- and look at all the details and all the facts.
- 7 Just looking further on down this list,
- 8 "Accurately disclosing information about the risks
- 9 of their drug in addition to the benefits being
- 10 marketed," that requires a sort of different
- analysis, but it wouldn't be impacted by the false
- 12 and misleading.
- 13 It should not be disguised, that we've
- 14 addressed in terms of the information being
- disclosed about what is being supported and so
- 16 forth.
- Good science and transparency.
- 18 So false and misleading would affect at
- 19 least one of these standards.
- Q. Okay. While I would enjoy discussing this
- 21 more, I want to be respectful of my colleagues and I
- 22 appreciate your patience with me and I will turn the
- 23 microphone over to someone else, but I suspect
- everyone is ready for a lunch break probably.
- MR. CHALOS: I hear the lunch carts rolling.

1 THE VIDEOGRAPHER: We are now going off the 2. video record. The time is currently 3 12:07 a.m. -- excuse me, p.m. (Recess from 12:07?p.m. until 12:44?p.m.) 4 5 THE VIDEOGRAPHER: We are now back on the 6 video record. The time is currently 12:44 p.m. 7 RECROSS-EXAMINATION 8 BY MS. RODGERS: 9 Dr. Perri, my name is Megan Rodgers. Again, Ο. 10 I'm with Convington & Burling representing McKesson. 11 I want to pick off where we left off -- pick 12 up where we left off yesterday, and I believe 13 yesterday you had testified that it was not 14 appropriate for a distributor to conduct kind of a 15 numbers-only analysis of a pharmacy's purchasing 16 history because it failed to take into account other 17 relevant considerations, right? 18 MR. CHALOS: Object to the form. I'm sorry. Are you reading from the 19 20 testimony that I provided yesterday or --21 Q. I am summarizing your testimony yesterday. 22 MR. CHALOS: Object to the form. 23 There was a lot in there. I need to take Α.

that, you know, piece by piece. I would like to

look at it, if you -- if you have it.

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25

- Q. I don't have your testimony in front of me.
- Let's take it piece by piece, though.
- 3 A. Okay.
- 4 Q. You would agree that it's not appropriate
- for a distributor to conduct a numbers-only analysis
- of a pharmacy's purchasing history, right?
- 7 MR. CHALOS: I object. That's outside of
- 8 the scope of the opinions that he's given in his
- 9 report, which is Exhibit 1 to this deposition.
- MS. RODGERS: And if you want to just have a
- 11 standing objection to these --
- MR. CHALOS: No, I'd like to make them. I
- think we need to make them each time for purposes
- of keeping the record clear.
- MS. RODGERS: Okay.
- MR. CHALOS: Standing -- standing -- I've
- 17 never found standing objections to be
- particularly effective because then it is not
- clear when I am making it, so I'd rather just
- 20 make them for each question.
- MS. RODGERS: Okay.
- 22 A. So in the questions that you were asking me
- yesterday, and one other attorney was asking me
- 24 yesterday, dealing with this issue of what is
- 25 appropriate for the wholesalers to do, I just -- I

- want to be clear on the record that I did not do any
- of that analysis or make any of those decisions or
- 3 have any opinions about that in this report that
- 4 I've written. I understand that you all have the
- 5 right to ask me questions about this, so I will try
- 6 to give you as good of answer as I can. I think, as
- 7 we established yesterday, though, this report was
- 8 written five years ago and there has been learning
- 9 that has occurred since then.
- 10 Q. There has been, I'm sorry, what?
- 11 A. There has been learning that has occurred
- 12 since then and I'm more familiar with the matters at
- 13 hand. However, I'm not an expert on suspicious
- order monitoring or what wholesalers should or
- 15 shouldn't do.
- Q. And when you say there has been learning on
- this matter, you mean that you've learned more
- information in connection with your participation in
- 19 this lawsuit?
- 20 A. The -- what I mean is that since this 2014
- case, I have become aware, as I mentioned yesterday,
- 22 that the DEA has put wholesalers sort of on notice
- that they need to do a better job of monitoring
- these orders. I don't know much about that.
- only -- that's the extent of what I know about it.

- Q. And you learned about that in connection
- with your participation in this lawsuit?
- 3 A. Yes.
- Q. Okay. And I think you testified yesterday
- 5 that it's not your understanding that any laws or
- 6 regulations changed since you wrote this expert
- 7 report, correct?
- 8 MR. CHALOS: Object to the form.
- 9 A. That is a pretty broad statement. I can
- 10 tell you that I think what I said yesterday was that
- I'm not aware that there have been any changes to
- the Controlled Substances Act since it was written.
- Q. Okay. And so let's -- let me point you to
- 14 Page 6 of your -- of Exhibit 10, which is your prior
- 15 expert report.
- 16 A. Okay.
- Q. And in Paragraph 26 you say: Based on my
- 18 review of the documents --
- 19 (Speakerphone interruption.)
- 20 (Discussion off the record.)
- THE VIDEOGRAPHER: We are now going off the
- video record. The time is currently 12:47 p.m.
- 23 (Recess from 12:47 a.m. until 12:49 p.m.)
- 24 THE VIDEOGRAPHER: We are now back on the
- video record. The time is currently 12:49 p.m.

- 1 BY MS. RODGERS:
- Q. Sorry about that interruption.
- 3 A. It's quite all right.
- 4 Q. I think we were looking at Paragraph 26, and
- in that paragraph you wrote: "Based on my review of
- the documents provided, the decision to reduce and
- 7 then suspend controlled substances deliveries to
- 8 Cherokee Pharmacy appears to have been based on two
- 9 primary considerations. First, a superficial
- internal analysis of the volume of purchases of
- 11 controlled substances by Cherokee Pharmacy."
- 12 Do you see that?
- 13 A. I do.
- Q. And why did you believe that that internal
- 15 analysis was superficial?
- 16 A. I don't recall. This is five years ago, so
- 17 I don't -- I don't really recall the documents or
- 18 why I would have used that term. Yeah.
- 19 Q. Okay. Let's look at Paragraph 27 then,
- where you wrote: "With respect to its own internal
- 21 monitoring, Smith tracked and allotted certain
- levels of controlled drugs to the pharmacies it
- 23 serviced. Part of this analysis was done by the
- 24 'Suspicious Order Monitoring System' that tracked
- not only actual product purchases but also attempted

- orders that were not filled by Smith in response to
- customer's orders. Smith's analysis was limited to
- 3 the numbers of units dispensed for specific time
- 4 periods."
- Is that refreshing your recollection?
- 6 A. A little bit it does, yes.
- 7 Q. Okay. And the paragraph goes on: "This
- 8 numbers-only oriented analysis does not take into
- 9 account the utilization patterns and the communities
- served by Cherokee Pharmacy, its new store location
- which was poised for growth, the demographics and/or
- changes in the prescribing community, the patient
- mix, incidence of disease or other factors (e.g.,
- insurance, formulary restrictions, or policies and
- procedures put in place by Cherokee Pharmacy to
- screen controlled substance prescriptions) impacting
- 17 controlled substances utilization."
- Do you see that?
- 19 A. I do.
- Q. And you agree that those are the limitations
- of the numbers-only oriented analysis conducted by
- the distributor, correct?
- MR. CHALOS: Object to the form.
- A. That, I don't know, because we were talking
- about something completely different. Where did the

- numbers-only -- where is that? Is that --
- Q. It's part of the sentence, sir. "This
- numbers-only oriented analysis..."
- 4 MR. CHALOS: Object to the form. Object, I
- 5 think it's misleading.
- 6 A. Okay. I see where you're at now. "The
- 7 numbers-only oriented analysis does not take into
- 8 account..."
- 9 Okay. And your question about that was?
- 10 Q. My question was you agree that the
- limitations you've identified here were the
- 12 limitations of that numbers-only oriented approach
- taken by the distributor in this case?
- MR. CHALOS: Hang on a second. Object to
- the form. I think that's misstating what this
- document says.
- 17 A. So I -- this does refresh my memory
- 18 slightly, and the thing that jumps out at me here
- is, as I recall in this case, Mr. Forshee, who was
- the pharmacist who owned Cherokee Pharmacy, and the
- 21 documents that I reviewed, he had placed multiple
- 22 orders for the exact same order that he had been
- 23 placing for his controlled substances. In other
- words, he ordered, let's say, five bottles of
- OxyContin on Saturday and it didn't come in on

- 1 Monday, so he placed that order again on Tuesday and
- it didn't come in on Wednesday, so he placed that
- order again on Thursday.
- 4 And what jumps out -- the recollection that
- 5 jumps out at me is that the way HD Smith -- I think
- it was -- it was either HD or JM Smith, I can't
- 7 remember which one it was. The way they -- they
- 8 counted all of those towards his quota, and I think
- that also referred to the "numbers-only," and I'm
- 10 not sure why they did that. I don't know what
- 11 processes or procedures they had in place, I just
- 12 know that from the documents that I saw and the
- testimony that came out, was that any order placed,
- whether it was filled or not, counted against his
- purchases of controlled sub -- which greatly
- inflated his apparent utilization, which the
- wholesaler did not take into account, and I think
- that was the real crux of what was going on here.
- 19 Q. Okay. I'm just going to ask this question
- again because that was a long answer that wasn't
- 21 entirely responsive.
- 22 So let me ask it a different --
- MR. CHALOS: Objection.
- 24 Q. Let me ask it a different way and see if you
- better understand my question.

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"A numbers-only oriented analysis does not
 1
      take into account the utilization patterns and the
 2.
      communities served by Cherokee Pharmacy, its new
 3
 4
      store location which was poised for growth, the
 5
     demographics and/or changes in the prescribing
      community, the patient mix, incidence of disease or
 6
      other factors."
 7
 8
              Do you agree that an analysis by a
     distributor should take those into account?
 9
10
              MR. CHALOS: Object to the form of the
11
         question, and the opinion its seeking is beyond
12
         the scope of the opinions that he's offered in
13
         this case.
14
         Α.
              So when I did the analysis back in 2014, I
15
      certainly agree that the wholesaler should have
16
      taken into account these factors. This was a very
17
     different case and very different issues than we
18
     have here, and as I said, I haven't provided any
      opinions about this in this matter.
19
20
              Do you agree those are always factors that
         Q.
      should be considered by a distributor?
21
22
              MR. CHALOS: Object to the form; also beyond
23
         the scope of the opinions he's offered in this
         case as reflected in Exhibit 1 to this
24
25
         deposition, his report.
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And just to be clear, I'm not asking you to
 1
      opine on whether any distributors' decision on any
 2.
 3
      given pharmacy was correct or incorrect right now.
 4
      I'm just asking as a general matter, do you agree
 5
     with the statement written here, that a numbers-only
     oriented analysis is flawed and that instead, you
 6
 7
      should take into account these other factors?
 8
              MR. CHALOS: I object to the form. I also
         object that it is beyond the scope of the
10
         opinions that he's offered in this case as
11
         reflected in his report, which is Exhibit
12
        Number 1 to this deposition.
              So the danger in me saying that these are
13
14
      the things that need to be reviewed will maybe lead
15
     people to think that I know the exact nature of what
16
     needs to be reviewed by a wholesaler, and I don't.
17
              I can tell you that in this case, based on
18
      the documents that I saw in this specific instance,
19
      it appeared that the decision that had been made had
20
     been made based on what I refer to in the paragraph
     as a numbers-only analysis and it did not take into
21
22
      consideration these factors. In that case, back in
23
      2014, I apparently felt that it should have.
24
              And are there situations you can think of
      where a distributor should not take those factors
25
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- 1 into account?
- MR. CHALOS: Hang on a second. Object to
- 3 the form, but I also object that it's beyond the
- 4 scope of the opinions that he's given in this
- 5 case as included in Exhibit Number 1 to this
- 6 deposition.
- 7 A. So I don't know. I would need to think
- 8 about that. I would need to figure out -- you know,
- 9 if I'm going to be asked questions about what I
- 10 think is -- you're referring to, and I know I
- 11 referred to it here, as suspicious order monitoring,
- which at the time was a new term to me, the answer
- would need to be analyzed. So should they always do
- 14 this? Should they never this? Should they do this
- 15 sometimes? I don't know.
- 16 Q. So let me ask you about the suspicious order
- 17 monitoring. Do you have expertise in suspicious
- 18 order monitoring?
- 19 A. I'm pretty sure I have said before that I do
- not.
- Q. Then why did you opine about it in this
- 22 case?
- A. Because this case wasn't about suspicious
- order monitoring. This case was about a pharmacist
- whose supply of all drugs was curtailed by his

- wholesaler, including controlled substances, and it
- was based on the wholesaler's lack of awareness of
- 3 the business operations at this pharmacy, which
- 4 placed the pharmacy in jeopardy, and in fact, as I
- 5 understand it, the pharmacy is no longer in
- 6 business, but the crux of this matter was the
- 7 wholesaler stopped providing drugs which made the
- 8 pharmacist not able to sell, generate revenue, and
- 9 then not able to pay their bills to the wholesaler.
- 10 So that was -- that was what was going on here.
- 11 This wasn't about suspicious order monitoring or
- 12 anything. It was just about a decision that the
- wholesaler made that, in my assessment, wasn't fair
- 14 to the pharmacy.
- Q. And the decision that you made, the decision
- 16 that -- sorry -- that you were assessing or
- 17 considering in this case, the -- in other words, the
- distributor's decision to stop providing controlled
- 19 substances to this pharmacy, part of the analysis,
- in your words, that went into that decision was done
- 21 by the suspicious order monitoring system of that
- 22 distributor, correct?
- MR. CHALOS: Object to the form.
- A. This is something that would have come from
- one of the documents that I reviewed. This was not

- 1 something that was based on my own knowledge. It
- was something that I learned as a process of
- 3 reviewing the materials in this case.
- 4 Q. So you put that into your report without
- 5 knowing or understanding what the suspicious order
- 6 monitoring system of the distributor was?
- 7 MR. CHALOS: Object to the form.
- 8 A. That's not fair at all. That's not fair at
- 9 all to say that. What I said was I learned about
- 10 this from the documents that I reviewed in this
- 11 case. So I don't know why you would say that I put
- it in there without learning about that system. I
- learned what I needed to know to formulate this
- opinion.
- 15 Q. So you learned about suspicious order
- 16 monitoring for this distributor?
- 17 A. I learned about what was happening in this
- case at this time. I was unaware that at that point
- in time there was a formal process known as
- 20 suspicious order monitoring. This was something
- 21 that at the time I thought was unique to HD Smith or
- 22 JM Smith, whoever it was.
- Q. And then you rendered a decision about the
- 24 distributor's analysis under their suspicious order
- 25 monitoring system, right?

- 1 MR. CHALOS: Object to the form.
- 2 A. No, no.
- MR. CHALOS: Misstates the document.
- 4 Q. What was your ultimate conclusion about the
- 5 wholesale distributor's decision to terminate the
- sale of controlled substances to this pharmacy?
- 7 I'm not trying to trick you but I think it's
- 8 in bold listed as Opinion V on Page 5.
- 9 A. I'm going to read the entire document
- 10 because I want to know what I'm talking about here.
- It's been five years since I've seen this and you're
- asking me a lot of questions and I don't know where
- they're coming from, so if you'll please bear with
- 14 me.
- 15 MS. RODGERS: Can we go off the record while
- he reviews this document?
- 17 A. I'm sorry, there is a question pending and
- 18 I'm reviewing the document in response to your
- 19 question.
- MS. RODGERS: I think we need to go off the
- 21 record for this.
- MR. CHALOS: I don't agree to go off the
- record.
- 24 SPEAKER: We have done that in other cases,
- like Doug Boothe, when --

```
MR. CHALOS: I don't know -- I don't know
 1
 2.
         anything about that, but I'm not -- I don't agree
         to go off the record here.
 3
 4
                   LADD: We have done that in other
 5
                We've gone off the record when the
        witness expresses the desire to review an entire
 7
         document. We've gone off the record to give the
 8
        witness a chance to review the document and gone
        back on the record once the witness has finished
10
         reviewing the document and is ready to answer
11
        questions about the document.
12
             MR. CHALOS: Well, I don't agree.
13
             MR. CIULLO: It's a courtesy we extended to
14
        the plaintiffs.
             MR. CHALOS: I know.
15
16
             MS. BAISCH: You didn't in my deposition.
17
             MR. CIULLO: You were deposed?
18
             MS. RODGERS: Okay. I'm going to preserve
19
        the objection so we can revisit this time
20
        allocation later. I think we should go off the
21
        record right now.
22
              MR. CHALOS: I don't agree.
23
             MS. RODGERS: I'm preserving the objection.
24
             MS. ZOLNER: At a minimum, can we keep track
25
        of the amount of time the witness is using to
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- review the document? (The time is 1:03 p.m.)
- 2 A. (The time is 1:05 p.m.) Okay. Thank you
- for giving me that time. If you could ask your
- 4 question again, I think I'm prepared to answer.
- 5 Q. Sure. What was your ultimate conclusion
- with respect to the distributor's decision to
- 7 terminate controlled substances here?
- 8 MR. CHALOS: Object to the form.
- 9 A. In this case, after having reviewed the
- document, which has refreshed my memory about what
- all was going on here, was that Smith Wholesale
- 12 suspended the sales of controlled substances to
- 13 Cherokee Pharmacy with what I referred to as an
- incomplete or flawed analysis.
- 15 Q. And it was incomplete or flawed because it
- 16 didn't take into account -- and I'm looking again at
- 17 Paragraph 7 -- 27 rather: "The utilization patterns
- in the community, its new store location which was
- 19 poised for growth, the demographics and/or changes
- in the prescribing community, the patient mix,
- incidence of disease, or other factors."
- 22 Correct?
- MR. CHALOS: Object to the form.
- A. That is what's written in the report, yes.
- Q. And you agree that business growth is a

- legitimate reason for increasing a pharmacy's
- permissible order limits?
- MR. CHALOS: Object to the form; also is
- 4 seeking opinions that are beyond the scope of the
- opinions that he's offered in this opioids
- 6 litigation as reflected in Exhibit Number 1 to
- 7 his deposition.
- 8 A. So at least in this matter I did -- I did
- 9 come to that conclusion based on the documents that
- I reviewed, that there were a number of factors that
- were not considered, one of which was the pharmacy
- was relatively new and it was in a growth phase,
- 13 yes.
- Q. Okay. And when you say in this paragraph
- 15 "changes in the prescribing communities," you meant
- 16 general increases in prescribing that were happening
- 17 around the country?
- 18 A. No, I don't believe so. I think this was
- 19 specifically to this case, which the changes in the
- 20 prescribing community in this instance had to do
- 21 with the -- if I remember correctly, and I think
- this is the case, there was a pain clinic with a
- nurse practitioner that had just opened near the
- hospital that was also adjacent to Cherokee
- 25 Pharmacy. I'm pretty sure that's what that relates

to, and this is five years ago, so --1 2. Okay. Yeah. And that would be a legitimate Q. reason for increasing a pharmacy's permissible order 3 limits? 4 5 MR. CHALOS: Object to the form of the question. I also object to the question on the 6 7 grounds that it is outside of the scope of the 8 opinions that Dr. Perri has given in the opioids litigation that we're here about today as 10 reflected in Exhibit Number 1 to this deposition. 11 So with respect to this case, the volume of Α. 12 documents that I looked at included a number of 13 factors why I felt as though the process that Smith 14 used to decide not -- to no longer sell 15 prescriptions to Cherokee Pharmacy, that was one of 16 the factors, but there were many. 17 Okay. And demographics, patient mix, and Q. 18 incidence of disease, those are also other factors that could lead a distributor to increase a 19 20 pharmacy's permissible order limits, right? 21 MR. CHALOS: Object to the form. Hang on 22 one second. Object to the form. I also object 23 to the question on the ground that it is outside

the scope of the opinions that he's given in the

opioids litigation as reflected in Exhibit

24

25

- 1 Number 1 to this deposition.
- 2 A. I hate to ask but you can you repeat that
- question again?
- 4 Q. Demographics, patient mix, an incidence of
- 5 disease, those are also factors that could lead a
- 6 distributor to increase a pharmacy's permissible
- 7 order limits, correct?
- MR. CHALOS: Same objections.
- A. Okay. So that -- that actually -- I'm glad
- I had you repeat that, because I thought I had
- detected something in there that concerned me.
- I did not evaluate increasing order limits
- under -- at any point in this case. The only
- 14 question that I had in front of me was the complete
- cut off of supply to that pharmacy of controlled
- 16 substances.
- So the question of should his allotments be
- increased was never on my radar in this case.
- 19 Q. Okay. That's -- let me withdraw and
- 20 rephrase.
- 21 A. Okay.
- 22 Q. Demographics, changes in the prescribing
- 23 community, and patient mix, incidence of disease,
- those are all factors that a distributor should
- consider in deciding whether to service a pharmacy

- with controlled substances?
- MR. CHALOS: Object to the form of the
- question. I also object on the ground that it is
- 4 seeking opinion testimony that's beyond the
- opinions that he's offered in this litigation as
- reflected in Exhibit Number 1 to this deposition.
- 7 A. So my answer to that is at least in this
- 8 case, I think those are things I should have
- 9 considered. I don't know beyond this.
- 10 Q. Okay. Let's look at the top of Page 7.
- 11 A. Okay.
- 12 Q. And I'm just going to read a statement and
- ask if you agree with it. It is the second
- paragraph on the -- on Page 7: "Pharmacies of
- different sizes and geographic locations have vastly
- different dispensing patterns due to their location,
- the number and types of prescribers nearby, and the
- demographics of the patients served. Each of these
- 19 variables can impact the volume and mix of
- 20 prescriptions dispensed."
- Do you agree with that statement?
- 22 A. I do.
- Q. Okay. In the second bullet point you note
- that the Pro Compliance report had based its
- assessment on spacial data, which was the distance

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of the prescriber or patient from the pharmacy.
 1
 2.
     Would you agree that that's not an adequate
      justification to withhold sale of controlled
 3
 4
      substances -- controlled substances to a pharmacy?
 5
              MR. CHALOS: Object to the form of the
                    I also object on the ground that it
 6
         question.
 7
         seeks opinion testimony beyond and outside the
 8
         scope of the opinions that he is offering in this
         litigation as reflected in Exhibit Number 1 to
10
         this deposition.
11
              So in this particular matter, there was a
         Α.
12
     unique concern that I had because of the location of
13
      Cherokee Pharmacy. Cherokee Pharmacy was located on
14
      the border between Georgia and Tennessee, and as
15
      such, they had a lot of patients that came -- and in
16
      addition to that, they were located near Chattanooga
17
     or outside Chattanooga, so they both drew patients
18
      from the Chattanooga area, as well as the rural
      areas around. So they had many patients that
19
20
      traveled 50 or 75 miles to get to their pharmacy.
      They had patients that traveled from out of state.
21
22
              And based on what I recall from this case
23
      and the Pro Compliance report, that Pro Compliance,
24
      the company that evaluated the pharmacy computer
25
      data for JM Smith, assessment was that the pharmacy
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- was suspicious, or whatever other word they were
- using, I don't recall what it was, but the
- 3 suspicious word is in this report, so I guess it
- 4 could be that, because -- or the orders were suspect
- 5 because of the distance that patients were traveling
- 6 to get to that pharmacy.
- 7 Now, to then not take that a step further
- 8 and look at it and say, "Oh, well, this pharmacy is
- 9 unique because of its geographic location, " seemed
- inappropriate to me and that's one of the basis for
- 11 the opinions that I expressed here.
- 12 Q. In other words, there is nothing inherently
- wrong with patients having to travel some distance,
- 14 you have to look a little closer at what's going on?
- MR. CHALOS: Object to the form, and object
- to the extent it's calling for an opinion that's
- beyond the scope of the opinions that he's
- offering in this litigation as reflected in
- 19 Exhibit Number 1 to this deposition.
- 20 A. So to answer your question, the -- if this
- was a pharmacy in Athens, Georgia, that has a number
- of pharmacies around and a completely different
- 23 geographic makeup, if patients are traveling 75 or
- 24 100 miles or coming from South Carolina or Tennessee
- or North Carolina to shop in Athens, that would be

- very suspicious to me. Again, I'm not basing this
 on any kind of expertise in the order -- in the area
- of knowing what a suspicious order looks like. I'm
- 4 basing it on the fact that I'm a pharmacist and I
- 5 have seen, at least in this case, the way rules --
- 6 whatever rules by whoever imposed them were being
- 7 applied, and I thought it was unfair in the case
- 8 against Cherokee Pharmacy.
- 9 Q. Okay. The third bullet point you wrote:
- 10 "The Pro Compliance report notes that Tennessee has
- one of the highest accidental drug overdose rates.
- 12 This is not relevant to the filling of legitimate
- prescriptions by licensed pharmacists acting on
- 14 medical providers' orders. While a significant
- problem, this must be addressed from a variety of
- 16 perspective, including through educating patients,
- not by withholding needed medications."
- Do you agree with that statement?
- MR. CHALOS: Object to the form. I also
- object to the extent it's calling for -- I object
- on the ground that it is calling for opinion
- testimony that's beyond the opinions that he's
- offered in this opioids litigation as reflected
- in Exhibit 1 to this deposition.
- 25 A. There is actually another factor that came

into play here in the fact that Mr. Forshee's 1 2. pharmacy actually drew from -- primarily from 3 Georgia and not Tennessee, and I'm not sure why 4 that's not noted here, but I do recall that from --5 as I'm getting more into this, I'm remembering more about this case. 6 But in general, I would agree that 7 8 pharmacies may have or they may not have procedures in place that can safequard patients and the filling 10 of prescriptions. We've all heard the term "pill 11 mills" before, and so if a pharmacy is just 12 indiscriminantly filling prescriptions without 13 vetting patients, not doing anything to protect 14 patients in any way, and I know from reviewing this 15 document over the last few minutes, Mr. Forshee had 16 an extensive procedure when a patient comes into the 17 pharmacy, where they collect page after page after 18 page of information to get to know the patient, to 19 help the patient understand how they were going to 20 meet their needs in term of providing pain medications and things like that. 21 22 So in this particular instance, I definitely 23 agree with this. I don't know if I could agree with this in another instance, but at least here for 24 Cherokee Pharmacy, I definitely agree with this. 25

You agree with the statement that I read to 1 2. you earlier: "This is not relevant to the filling 3 of legitimate prescriptions by licensed pharmacists acting on medical providers' orders. 5 significant problem -- " again the accidental drug overdose rates -- "this must be addressed from a 6 7 variety of perspectives, including through educating 8 patients, not by withholding needed medications." 9 MR. CHALOS: Object to the form, and I also 10 object to the extent it's calling for opinion 11 testimony beyond the scope of the opinions that 12 he's offering in this case as reflected in 13 Exhibit Number 1 to this deposition. 14 Α. So to the extent that this -- these two 15 sentences relate to Cherokee Pharmacy, I definitely 16 agree with them. 17 Q. Thank you. If you look at the next bullet 18 point, you note that: "The Pro Compliance report 19 does not mention that Tennessee is the 3rd highest 20 in the US in terms of utilization of all prescription medications..." 21 22 And then I'm skipping down to the next 23 paragraph there. Do you agree that that "highlights 24 that average numbers of prescriptions per capita in 25 Tennessee will be different than the rates reported

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in other states and national averages"?

MR. CHALOS: Object to the form. I also

object to the extent it's calling for -- I object

on the ground that it is calling for opinions
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- that are beyond to scope of the opinions he's
- offered in this case.
- 7 A. So is your question do I agree that
- 8 Tennessee is third, is that --
- 9 Q. I'm saying first, do you agree that the fact
- that Tennessee is third highest in the US in term of
- 11 utilization of all prescription medications means
- that the average numbers of prescriptions per capita
- in Tennessee will be different than the rates
- 14 reported in other states and national averages?
- MR. CHALOS: Object to the form. I also
- object on the ground that it is seeking expert
- testimony and opinions beyond the scope of the
- opinions he's offered in this case.
- 19 A. So that was the -- the footnote to that is
- referenced to the Kaiser Family Foundation, so I
- 21 will defer to them to assess whether that's accurate
- or not. I certainly think the Kaiser Family
- Foundation is a well-respected repository of date
- regarding this type of utilization.
- With regard to the next statement, I think

- that flows from the citation from Kaiser.
- Q. Which next -- that "interestingly"?
- 3 A. Yes.
- Q. Okay. Let me ask this a different way. Why
- 5 did you include this point, that Tennessee is the
- 6 third highest in the US in terms of utilization of
- 7 all prescription medications in your report?
- 8 A. So I guess the reason that was included was
- 9 because the drug utilization in different parts of
- 10 the country, and we've seen in this case that Ohio
- 11 has a fairly high utilization of certain drugs,
- other parts of the country have less utilization, so
- 13 I think sensitivity should be applied at least in
- 14 this case of Cherokee Pharmacy, that I think was
- treated unfairly by the wholesaler, based on this
- 16 report and my recollection of what I did in this
- case, that the -- that whatever system the
- wholesaler had in place, whatever data they were
- using should have been sensitive to the fact that
- they are in a high drug utilization area, and that
- 21 mean -- that might mean that they are more sensitive
- or it might mean that they are less sensitive, but
- 23 it should have at least been considered and it was
- 24 not apparently considered.
- Q. Okay. It should be considered even in the

- 1 context of hydrocodone, which is I believe what
- prompted this report?
- MR. CHALOS: Object to the form and object
- 4 to the extent it's seeking an opinion that is
- beyond the scope of the opinions he's offering in
- the current litigation as reflected in Exhibit 1
- 7 to this deposition.
- 8 A. So for clarification, is hydrocodone the
- 9 drug that was at issue in this case?
- 10 Q. I believe it's actually oxycodone in
- 11 Paragraph 29.
- 12 A. Okay.
- MR. CHALOS: Same objection.
- 14 A. I'm sorry. Is there a question now?
- 15 Q. Sure. My question is is your opinion that
- 16 distributors should have considered the fact that
- 17 Tennessee is the third highest in the US in terms of
- utilization of all prescription medications when
- making a decision about whether to terminate the
- sale of controlled substances?
- MR. CHALOS: Object to the form. Object to
- that question on the ground that it's seeking
- opinion testimony that is outside the scope of
- the opinions he's offering in this litigation as
- reflected in Exhibit Number 1 to this deposition.

- 1 A. So I think I just answered that. So if I
- 2 didn't -- if you don't think I did, then I need to
- make sure we're communicating properly here, because
- 4 I said I think with regard to this case that
- 5 something that --
- 6 MR. CHALOS: This case being?
- 7 A. I'm sorry. Yes, the Cherokee Pharmacy case,
- 8 that it's something that the wholesaler should have
- 9 considered, Pro Compliance should have considered,
- but they did not apparently consider, and I said it
- 11 could be that they would be more sensitive to
- utilization because it's a high-use area, or they
- might be less sensitive because it's a high-use
- 14 area. So that was, I think, what the gist of my
- answer was before. Or is that the response as you
- 16 recall it?
- 17 Q. Yes, I believe that was to a different
- 18 section, but that -- I appreciate your response now.
- 19 Thank you. I want to ask you just one other
- 20 question about a document that you cite at
- Footnote 8, and I brought a copy of that and marked
- 22 it as Exhibit 21.
- 23 (Perri Exhibit 21 was marked for
- 24 identification.)
- 25 BY MS. RODGERS:

- 1 Q. This is an article in Pharmacist.com, which
- is titled: "Pharmacists turn away legitimate pain
- 3 patients as wholesalers limit shipments of
- 4 controlled substances."
- You've seen this document before, I take it?
- 6 A. Yes.
- 7 Q. This article?
- 8 A. Yes.
- 9 Q. What is the National Community Pharmacists
- 10 Association?
- 11 A. NCPA is a group of -- I believe NCPA is the
- 12 association that used to be the National Association
- of Retail Druggists and they've changed their name
- 14 to National Community Pharmacists Association, and
- they represent our nation's independent community
- pharmacies and some small chains, I think.
- 17 Q. Okay. And are you or have you been -- have
- you ever been a member of that association?
- 19 A. I've never been a member of NCPA or NARD;
- however, during the early part of my career I was
- frequently asked to speak at their meetings on
- issues related to helping community pharmacists run
- their businesses more efficiently, especially
- 24 related to marketing topics.
- Q. And I just want to direct your attention to

- right after the header "NCPA: The pendulum has
- 2 really swung too far."
- 3 A. Okay.
- 4 Q. Where it says: An online survey released in
- 5 January by the National Community Pharmacists
- 6 Association found that three out of four (75%) of
- 7 the nearly 1,100 responding pharmacies had
- 8 experienced three or more delays or issues caused by
- 9 stopping shipments -- stopped shipments of their
- 10 controlled substances over the past 18 months.
- I'm just going to stop there.
- 12 A. Okay.
- Q. Would you -- is it your opinion that that's
- a problem, would you agree that that's a problem?
- MR. CHALOS: Object to the form. I also
- object on the ground that it seeks opinion
- testimony beyond the scope of the opinions that
- he has offered in this case as reflected in
- 19 Exhibit 1 to his deposition.
- 20 A. Yeah. So to answer your question, I -- you
- 21 know, I've cited this document in this report to
- show that this wasn't a problem just for Cherokee
- 23 Pharmacy, but that other pharmacies are reporting
- the same kinds of problems. I did no analysis or
- evaluation of that, I didn't verify those numbers,

- so I really can't tell you what they're all about
- other than it's a report from a fairly reputable
- 3 trade magazine that says, hey, this is a problem for
- 4 other pharmacies, and I think that's the real reason
- 5 why I cited it here.
- As far as whether I agree with it or not, I
- 7 certainly think that there is a heightened
- 8 sensitivity on the part of community pharmacists in
- 9 the area of being able to meet their patients'
- 10 needs. I know that some pharmacies feel as though
- 11 the behavior of certain stores, certain groups of
- stores, has negatively impacted the marketplace and
- that's why they feel like their orders are being
- 14 reduced or cut back.
- 15 So I think this is a real issue. I don't
- 16 really have any opinions about it or any analysis
- 17 associated with it, but with respect to Cherokee
- Pharmacy, this was something I felt as though
- 19 would -- to highlight for whoever was reading this
- 20 report at the time, the fact that this is not just
- an isolated incidence, perhaps there are other
- incidences that are occurring.
- MS. RODGERS: Okay. I have no further
- questions. Thank you for your time.
- THE WITNESS: Thank you.

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1
              THE VIDEOGRAPHER: We are now going off the
 2.
         video record. The time is currently 1:23 p.m.
 3
            (Recess from 1:23 p.m. until 1:27?p.m.)
 4
              THE VIDEOGRAPHER: We are now back on the
 5
         video record with the beginning of Media
 6
         Number 4.
                    The time is currently 1:27 p.m.
 7
                       RECROSS-EXAMINATION
 8
     BY MR. LADD:
 9
         Ο.
              Good afternoon, Mr. Perri. My name again is
10
     Matthew Ladd, and we spoke yesterday, from Morgan
11
     Lewis representing Rite Aid. I have a handful of
12
     questions for you as you correctly intuited
13
      concerning your prior expert report in Cherokee
14
      Pharmacy which has been marked Exhibit 10.
15
              Do you still have that exhibit in front of
16
     you?
17
              Yes, I do.
         Α.
18
              Could you turn, please, to Page 4 of that
19
      exhibit, and specifically let me direct your
20
      attention to Paragraph 19.
21
        Α.
              Okay.
22
         Q.
              Do you see where I am?
23
        Α.
             Yes.
              If you would look down, the fourth sentence
24
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beginning "If the pharmacist believes," do you see

25

- 1 that sentence?
- 2 A. Yes, I do.
- Q. And to save time, I'll just read it into the
- 4 record. You wrote here: "If a pharmacist believes
- 5 that a particular drug might not be the best therapy
- for a patient, they may explain their findings to
- 7 the medical provider, but the final decision is that
- 8 of the medical provider and the order must be filled
- 9 exactly as written."
- Did I read that sentence correctly?
- 11 A. Yes.
- 12 Q. And was this part of the opinion in your
- expert report that you submitted in the Cherokee
- 14 Pharmacy case?
- 15 A. Yes, it was.
- Q. And did you agree with this statement when
- 17 you wrote it?
- 18 A. Of course. I agree with it now.
- 19 Q. Thank you. If you look to the next
- statement, I'll ask a series of similar questions:
- 21 "Pharmacists have a professional duty to provide the
- medications selected by the prescriber when a
- legitimate patient-prescriber relationship exists."
- Did I read that sentence correctly?
- 25 A. Yes, you did.

- Q. And did you agree with that statement when
- you wrote your prior report?
- A. Yeah. And I would like to just add, though,
- 4 that this is, with respect to the bigger context of
- 5 the pharmacist's duty when they bring a patient into
- the pharmacy, the -- this doesn't apply to any
- 7 particular drug or drug category. This is for all
- 8 drugs.
- 9 Q. I understand this is for all drugs.
- 10 A. Right.
- 11 Q. Including controlled substances?
- 12 A. Yes.
- Q. Including opioids?
- 14 A. Yes, that's right.
- Q. And you agreed with this statement when you
- 16 wrote it?
- 17 A. I did.
- Q. And you agree with this statement now?
- 19 A. It's part of the Pharmacy Practice Act, yes.
- Q. Thank you. If you could turn to the next
- page, at the top of Page 5, the last sentence in
- 22 Paragraph 20, you wrote: "The role of the
- 23 pharmacist is not one of second quessing medical
- 24 providers, but rather to work to ensure appropriate
- drug therapy, the integrity of the prescription

- 1 process, and to guarantee the delivery of
- 2 medications to patients."
- 3 Did I read that sentence correctly?
- 4 A. Yes.
- 5 Q. And did you agree with that statement when
- 6 you wrote it?
- 7 A. There's a lot in there but I did agree with
- 8 it then and I do agree with it now.
- 9 Q. Thank you. In other words, the point is
- 10 pharmacists should not interfere with the
- 11 physician-patient relationship; is that correct?
- MR. CHALOS: Object to the form. It also is
- asking for opinions outside of the opinions he's
- offered in this litigation, the opioids
- 15 litigation, as reflected in Exhibit 1 to his
- deposition.
- Q. And to rephrase, Dr. Perri, if I may, the --
- 18 I'll withdraw that question and ask another one.
- 19 Part of your opinion in this prior report
- 20 was that pharmacists should not interfere with the
- 21 physician-patient relationship; is that correct?
- MR. CHALOS: Object to the form.
- A. So, actually, no, that's not -- that's not
- really what I'm trying to imply here. When you say
- it should not interfere, it's more like they should

intervene in a positive and appropriate way when 1 2. there is a problem. 3 So if you go back to the paragraphs that we 4 looked at just before, the duty to ensure that there 5 is a legitimate prescriber-patient relationship, the duty to do a prospective drug utilization review and 6 7 ensure that the medication that is being prescribed 8 is not going to do any harm to the patient, these -if you intervene in that, you're not interfering 9 10 with the patient-physician relationship, you are 11 intervening to ensure appropriate care. So I 12 disagree with your use of the word interfering. 13 But with that being said, I think that the 14 pharmacist has the role as I've described in my 15 answer, and also the general Pharmacy Practice Act 16 that we all work underneath the authority of, 17 certainly it would support these statements. 18 And to be clear, and just to give some context to this statement that you just gave, your 19 20 opinion in this report was that -- part of your opinion in this report was that when a legitimate 21 patient-prescriber relationship exists, pharmacists 22 23 have a professional duty to provide the medication selected by the prescriber; is that correct? 24 25 MR. CHALOS: Object to the form.

- 1 A. Yes, and -- but there is two parts to that,
- and the second part of it is that the pharmacist's
- duty extends beyond just the legitimacy of the
- 4 patient-prescriber relationship, even though that's
- 5 the first part and if it's not met, then everything
- stop, but the second part is, is to ensure that the
- 7 drugs is not going to do any harm. So though -- but
- 8 those things, they have to go together, in my mind.
- 9 Q. I understand. Thank you, Dr. Perri, for
- 10 clarifying.
- 11 A. Thank you.
- 12 Q. Can you go to Paragraph 25 of this expert
- 13 report, please?
- 14 A. Okay.
- 15 Q. And you discussed yesterday with
- 16 Ms. Rodgers, just to refresh your recollection, this
- 17 particular part of the report dealt with a
- distributor, Smith Wholesale, that in this case
- unilaterally ceased providing controlled substances
- to Cherokee Pharmacy; is that correct?
- 21 A. Yes.
- Q. And you write in your report, and I'm
- looking now at the last sentence before the two
- 24 bullet points: "This action had two significant and
- immediate effects on the operation of the pharmacy

and its patients." 1 2. Do you see that sentence? 3 Α. Yes. 4 Ο. And did I read that correctly? 5 Α. Yes. Thank you. And one of the significant and 6 Q. 7 immediate effects that you noted in your prior 8 report was that the pharmacy could not provide 9 needed medications to its patients; is that correct? 10 Α. Yes. 11 And the second significant and immediate Ο. 12 effect of the distributor unilaterally ceasing to 13 provide controlled substances to the pharmacy was 14 that legitimate patients with serious medical conditions were unable to obtain their controlled 15 16 substances medication from the pharmacy; is that 17 right? 18 Α. Yes. 19 Q. Thank you. 20 Α. So --21 Can you go to the next paragraph, please? Q. 22 MR. CHALOS: Hold on. Do you have 23 something --24 THE WITNESS: No, it's okay. I can -- I'll 25 bring this up.

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1
              If you looked at Paragraph 26 at the top of
 2.
      Page 6, is it fair to say that this particular
 3
     paragraph, based on the review of your prior report
 4
      that you were conducting during Ms. Rodgers'
 5
      examination, deals with two separate analyses that
 6
     had been done, one by the distributor and one by a
 7
      third party, Pro Compliance; is that correct?
 8
              MR. CHALOS: Object to the form.
 9
              It seems to me that JM Smith did some kind
10
11
     of a superficial analysis and that they got a Pro
12
      Compliance report. There were a couple of issues
13
      that were going on here with regard to these -- the
14
      timing of all of this. Smith -- and there is one
15
     other issue that I feel like I have to tell you as
16
     well because it has bearing on this whole report and
17
      why this incident came about.
18
              But the initial analysis, whatever Smith
19
     did, and I don't know exactly -- I don't recall and
20
      I don't know if I ever knew exactly what they did,
     but whatever it was, it prompted them to order this
21
      Pro Compliance report, and Mr. Forshee didn't want
22
23
      to do the Pro Compliance report for some reason, as
24
      I recall, because he felt like it was a violation of
25
     HIPAA in some way, because the wholesaler would then
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- 1 be looking at his actual patient data in his
- 2 computer: Names, addresses, phone numbers, ZIP
- 3 codes, all that kind of stuff.
- 4 So there was this back-and-forth between
- 5 them, and Mr. Young, who was the Smith
- 6 representative -- what has -- what has occurred to
- 7 me in all of this is that nothing -- something that
- 8 hasn't come up at all was the real reason that came
- out in this whole case about why Mr. Forshee's
- 10 supply was being cut was because Smith didn't want
- to do business with him anymore because he got very
- 12 rude with him on the telephone, and these were all
- things that were being acting as if they were a
- smoke screen to cloud the issue of why they were
- really cutting him off as a supplier.
- So there were these other layers to what was
- 17 going on, and I don't think that's come out before,
- and really, as I'm getting back into this, I'm just
- 19 remembering more and more about the case. So --
- 20 Q. I --
- 21 A. I was going to say but to answer your
- 22 question, there were -- there were two things that
- 23 were related to the orders, there was the conflict
- 24 between Mr. Forshee, as far as the releasing his
- patient data to a third party that he didn't have

- any real knowledge of, and then the issues
- 2 related -- also the issues related to Mr. Forshee's
- 3 belief that the wholesaler shouldn't be interfering
- 4 with his patient relationships.
- 5 So there were four things, I think. You
- 6 mentioned two.
- 7 Q. Thank you, Dr. Perri. So just to go back to
- 8 my question, there were two analyses referred to in
- 9 this particular paragraph; is that correct, one
- 10 superficial internal analysis done by the
- distributor, and one partial analysis of dispensing
- 12 statistics provided by Pro Compliance?
- 13 A. So to that question, yes, there were two
- 14 analyses. I thought the prior question had asked me
- 15 what the factors were.
- 16 Q. And I apologize if I was unclear, but this
- paragraph is just addressing these two analyses, one
- by the distributor and one by Pro Compliance; is
- 19 that right?
- 20 A. That's right.
- Q. Okay. And in your opinion in this report
- 22 and I'm just reading from your report here, in your
- opinion both the distributor's internal analysis and
- 24 the Pro Compliance report had serious flaws that
- rendered these analyses largely useless; is that

- 1 correct?
- MR. CHALOS: Where is that? Where are you
- 3 reading from?
- 4 Q. So this is from the fourth sentence of
- 5 Paragraph 26.
- 6 A. That's what I said at the time, yes.
- 7 Q. And they were largely useless in evaluating
- 8 the appropriateness of the dispensing of controlled
- 9 substances at the pharmacy; is that right?
- 10 A. Based on the documents I had seen in this
- 11 matter, that's -- that was the conclusion I came to.
- 12 Q. Thank you, Dr. Perri. And just because I'm
- not positive we got this on the record yesterday, if
- 14 you will go to Paragraph 29.
- 15 A. Okay.
- 16 Q. In your expert report in this case, Cherokee
- 17 Pharmacy, you stated that the distributor lowered
- the allotment for oxycodone by as much as 50
- 19 percent; is that correct?
- 20 A. You know, I don't recall that but I see that
- it's in the report here in Paragraph 29.
- Q. Okay. Thank you. And as a result of that,
- 23 Cherokee Pharmacy could not fill all prescription
- requests for oxycodone; is that right?
- MR. CHALOS: Object to the form. I think

- that misstates the -- what this is saying here.
- Q. So let me try the question a different way.
- 3 I'll read directly from your report.
- 4 A. Okay.
- 5 Q. "The fact that the distributor lowered the
- 6 allotment for oxycodone to Cherokee Pharmacy by as
- 7 much as 50 percent meant that Cherokee Pharmacy
- 8 could not fill all prescription requests for this
- 9 product."
- 10 Is that correct?
- MR. CHALOS: Object to the form; misstates
- 12 the document.
- 13 A. So the real issue here, as I'm looking at
- 14 this, was that not only they were -- they were
- 15 cutting the quota, but they were also not telling
- 16 Mr. Forshee what his new magic number was going to
- 17 be.
- 18 Q. I understand.
- 19 A. So he ran the risk of if he placed an order
- and it exceeded his allotment, that he was going to
- 21 then be held accountable for that order that he
- never received once again, as he was in prior
- orders, which was going to add to the demerits
- 24 against him and his pharmacy in the overall system
- 25 that Smith was using.

- 1 So that actually contributed to my questions
- about how the Smith system could be effective in
- actually doing what it was purporting to do.
- 4 Q. Thank you. That's helpful. And because of
- 5 that, you opined in your report: "Patients would
- 6 have to seek to have their medication filled
- 7 elsewhere or go without needed medication."
- 8 Is that correct?
- 9 MR. CHALOS: Object to the form.
- 10 A. In the event that these things actually
- 11 happened and he didn't receive an order, and he
- didn't have inventory to fill it, yes, they would
- have needed to go somewhere else.
- 14 Q. Thank you, Dr. Perri. Could you turn to the
- 15 next page?
- 16 A. Yes.
- Q. Actually, go two more pages in, on Page 8,
- and then we'll jump back because I have a few more
- 19 questions about the Pro Compliance report that you
- discussed with Ms. Rodgers just a few moment ago.
- 21 A. Okay.
- Q. My first question has to do with the
- conclusion that you arrived at in Paragraph 32. You
- 24 stated here: "The actions taken by Smith Drug
- 25 Company to arbitrarily impose restrictions on

- dispensing of controlled substances by Cherokee
- 2 Pharmacy interfered with its patients' ability to
- 3 get needed medications."
- 4 Is that correct?
- 5 MR. CHALOS: Object to the form.
- 6 A. That's the conclusion that I drew here.
- 7 Q. Thank you. And just so we have it on the
- 8 record, did you alter or change this opinion in any
- 9 way after you submitted it, to your recollection?
- MR. CHALOS: Object to the form.
- 11 A. I don't know that there would even be a
- mechanism to do that. You mean like filing a
- supplemental report or something like that?
- Q. Correct. You're not aware of having changed
- or altered your opinions in this case in any way?
- 16 A. No.
- 17 Q. Thank you. If you could look back on Page 7
- 18 to the discussion of the Pro Compliance report, and
- 19 specifically the second bullet point, you spoke a
- few moments ago with Ms. Rodgers concerning the Pro
- 21 Compliance report basing its assessment on spacial
- 22 data; is that correct?
- MR. CHALOS: Object to the form; a vague,
- 24 unclear question.
- Q. You can answer.

- 1 A. I'm looking for the word "spacial" so I --
- oh, there it is. Gotcha. The second bullet point.
- 3 Okay.
- 4 Yes.
- 5 Q. You remember discussing that with
- 6 Ms. Rodgers just a few minutes ago?
- 7 A. Yes.
- Q. And if you look to the paragraph directly
- 9 after that beginning with the sentence "This is
- 10 flawed," do you see that?
- 11 A. Yes, I do.
- 12 O. You wrote: "This is flawed because no
- 13 standards are presented nor assessment of the actual
- 14 distances reported. This is likely due to the lack
- of defensible benchmark for these statistics given
- the vast differences that would be seen between
- 17 rural and metropolitan areas."
- Do you see that?
- 19 A. I see that.
- Q. My question for you is in this case, what
- would have been a defensible benchmark, in your
- 22 opinion?
- MR. CHALOS: Object to the form. Are you
- talk -- when you say "in this case," that's my
- beef with the question. Are you talking about in

- this case we are here about today, or in Smith?
- MR. LADD: In the case in Smith, in Smith.
- MR. CHALOS: Okay. Yeah, because --
- 4 MR. LADD: In which he wrote the prior
- 5 report. Understood.
- 6 MR. CHALOS: Okay.
- 7 BY MR. LADD:
- 8 Q. In Smith, what would a -- what would a
- defensible benchmark have looked like, in your
- 10 opinion?
- 11 A. You know, I wasn't asked to come up with the
- 12 right answer, I was just making a notation here that
- they hadn't developed a benchmark, they just said
- that the patients were traveling too far but they
- didn't say how far that was or why. So I don't know
- what the right number would be.
- 17 I do know that it would be different than an
- in-town center city pharmacy because of the rural
- 19 location, and distance between two much bigger
- 20 cities than where Cherokee Pharmacy is located.
- Q. Thank you. And I believe you said a moment
- ago when you were being asked questions by
- Ms. Rodgers that this was an unusual situation
- 24 because there was was a rural community that was
- located between two larger cities?

- 1 A. And on the border.
- 2 Q. Is that correct?
- A. Right. And on the border.
- 4 Q. And on the border. So is it your
- 5 understanding that this particular city, Cleveland,
- 6 Tennessee, was the only community in the United
- 7 States that was both on the border of a state and
- 8 located between two much larger cities?
- 9 A. It's the only one in Cleveland, Tennessee
- 10 that has those characteristics. I don't know about
- 11 the rest of the country.
- 12 Q. I understand. Is it your understanding that
- there are other rural communities in the United
- 14 States that are located between two much larger
- 15 cities?
- 16 A. I'm sure that we could identify some if we
- 17 pulled out a map. I think the point isn't whether
- there is other cities or not, the point is, is
- whatever rules were in place, were they being
- 20 applied appropriately to Cleveland -- Cleveland,
- 21 Tennessee and to Cherokee Pharmacy, which was the
- 22 analysis that I was trying to do in the Cherokee
- 23 Pharmacy case.
- Q. I understand. But in your view in this
- prior expert report, part of the reason there was a

- lock of a defensible benchmark was that the
- dispensing analysis that took place did not take
- into account the particular geographical
- 4 characteristics of the pharmacy in question; is that
- 5 right?
- 6 A. I think, basically, that is something I
- 7 would agree with.
- 8 Q. Okay. And so in this -- so your
- 9 understanding at the time was that for a dispensing
- analysis of a pharmacy's dispensing practices to be
- 11 accurate or to be accurate as possible, it would
- need to take into account whatever geographical
- particularities or characteristics that pharmacy
- 14 had?
- MR. CHALOS: Object to the form, and object
- to the extent it's seeking opinions here in our
- case, the opioids case, that are beyond the scope
- of his opinions as reflected in Exhibit 1.
- 19 A. So the answer to your question is, you know,
- I don't know what needs to be done for other stores.
- I did a pretty thorough analysis here of Cherokee
- 22 Pharmacy back when this all happened and I had a lot
- of data, I could look at a lot of things. I looked
- 24 at prescription numbers, the volumes, the actual
- 25 numbers of controlled substances that Mr. Forshee

- was ordering. So I had a lot of information on that
- 2 so I could actually make an informed decision about
- whether what was happening to him seemed to be
- 4 appropriate or not.
- Beyond the scope of his store, I can't make
- 6 any conclusions or have any opinions about what's
- 7 right or wrong for other stores or what should be
- 8 done at the wholesaler level or any other level.
- 9 Q. Understood. But could you say at this time,
- when you wrote this report, to a reasonable degree
- of certainty that a dispensing analysis of a
- pharmacy would likely be more accurate if it took
- into account geographical characteristics of a
- 14 particular pharmacy than if it did not?
- MR. CHALOS: Object to the form, and object
- to the extent it's calling for opinion testimony
- beyond the scope of the opinions he's offering in
- the opioids litigation.
- 19 A. So with respect to Cherokee, I definitely
- 20 agree with that. I don't know beyond that because
- 21 there may be more -- there may be some
- one-size-fits-all that's appropriate. I haven't
- 23 undertaken to study that. I'm not an expert in that
- 24 area and I haven't looked at it at Cherokee nor in
- our case today, the opioid case.

- 1 Q. You're not aware of any one-size-fits-all
- dispensing analysis that would be appropriate in
- 3 Cherokee or any other case?
- 4 MR. CHALOS: Object to the form. I also
- object to the extent it's -- object on the ground
- that it is seeking opinion testimony beyond the
- 7 scope of the opinions he's offering in this
- 8 litigation as reflected in Exhibit 1 to his
- 9 deposition.
- 10 A. So I guess what I'm saying is I leave open
- 11 the possibility that there is some rule that could
- be applied, and I think you referred to it as a
- dispensing analysis.
- 14 Q. Yeah. Yeah.
- 15 A. And I think that's the Pro Compliance
- report, is a dispensing analysis. Am I correct in
- 17 that assumption?
- 18 Q. Yes, that's correct.
- 19 A. So if -- I would leave open the possibility
- that there is some one-size-fits-all rule that could
- 21 be developed that would be an initial or prescreen
- for any potential problems in a dispensing analysis.
- 23 Again, I don't know what that rule might be, I
- haven't undertaken to analyze that, and I'm not an
- expert in that area, and I didn't provide any

- opinions in the opioid case about things like that.
- Q. And just be clear, you're not aware of any
- 3 such one-size-fits-all rule as you sit here today?
- 4 A. Well, I think what Cherokee was being
- subjected to was a one-size-fits-all rule, which was
- if you are traveling more than 25 miles, and I think
- 7 that's what we assumed they were using at the time,
- gives just as my recollection is, is that number came into
- 9 my head, that seems to be what they were using, but
- it didn't apply to Cherokee.
- So it would -- that would at least be
- evidence in my mind that a one-size-fits-all doesn't
- work for anybody.
- MR. LADD: Thank you, Dr. Perri. Those are
- all the questions I have for you today.
- 16 THE VIDEOGRAPHER: We are now going off the
- video record. The time is currently 1:47 p.m.
- 18 (Recess from 1:47 p.m. until 1:49?p.m.)
- THE VIDEOGRAPHER: We are now back on the
- video record. The time is currently 1:49 p.m.
- 21 CROSS-EXAMINATION
- 22 BY MS. COATES:
- Q. Hello, Dr. Perri. My name is Melissa Coates
- 24 and I represent the Teva defendants in this matter.
- I am going to try my best not to retread any ground

- 1 but stick to some questions specific to my client.
- 2 A. Okay.
- Q. And I'm -- am I correct, based on what I
- 4 heard in your testimony so far, that you are not
- offering a Teva-specific opinion in your report or
- 6 your testimony?
- 7 A. Yes.
- 8 Q. And similarly, you are not offering any
- 9 Cephalon-specific opinion in your report or your
- 10 testimony?
- 11 A. Yes.
- 12 Q. Okay. If we could turn -- we can go back to
- 13 Exhibit 1 to your report, and if we could turn to
- 14 Paragraph 165.
- 15 A. Okay.
- 16 Q. All right. This is under Subsection G,
- 17 Defendants' Generic Marketing; is that correct?
- 18 A. Yes, it is.
- 19 Q. And it looks to me like Subsection G goes
- through Paragraph 182; is that correct?
- 21 A. Yes.
- Q. And does this Section G, Paragraphs 165
- through 182, represent the entirety of the opinions
- you're giving on generic marketing, generics
- 25 marketing?

- 1 MR. CHALOS: Object to the form.
- 2 A. I think so. I think the only other place
- 3 there might be something related to marketing of
- 4 generics would be in the section on the distribution
- 5 channels, the supply chain earlier in the report,
- 6 but it wouldn't be anything different. It just
- 7 might be supplemental.
- Q. Okay. And what do you mean, just so that we
- 9 can be clear, when you refer to generic marketing?
- 10 A. So the marketing for brand name
- 11 pharmaceuticals and marketing for generics, in my
- 12 experience, is slightly different.
- 13 Q. Okay.
- 14 A. So I felt as though I should distinguish
- between the two in the report. So to the extent
- 16 that different methods are used or different themes
- 17 are used, I wanted to have a section that
- specifically related to the themes used with
- 19 generics.
- Q. Okay. And this is specific to generic
- 21 prescription medicines, and in this case opioids,
- it's not generic in the sense of nonspecific or
- unbranded, it's generic prescription medicines and
- 24 opioids?
- 25 A. Yes.

- 1 Q. All right. If we could turn to Paragraph
- 2 173.
- 3 A. Okay.
- 4 Q. And the last sentence of that paragraph
- 5 reads: The key marketing messages are focused on
- 6 competitive prices and the assurance of consistent
- 7 supply of quality generic medicines -- medications.
- 8 Did I read that correctly?
- 9 A. Yes, you did.
- 10 Q. Thank you. And I think you reference that
- just a minute ago, that those marketing messages are
- different than what you've seen with the branded
- marketing messages; is that correct?
- 14 A. Yes.
- 15 Q. Okay. And generic manufacturers do not
- promote the safety, efficacy, or benefits of their
- 17 generic medications; is that correct?
- MR. CHALOS: Object to the form.
- 19 A. I would agree that they generally don't do
- 20 that, but if there is not -- I can't say that that's
- 21 never done with respect to generics. And if we
- qualify that just a little bit, for example,
- 23 sometimes with generics there are -- references are
- 24 made to other products or comparable products, the
- branded product itself. So when that occurs, the

- 1 generic is sort of linking itself to the branded
- 2 rather than just standing alone on its own. So with
- 3 those qualifications -- generally, I completely
- 4 agree with this, and this is what I see in the vast
- 5 majority of the marketing messages associated with
- 6 generics that I saw in the opioid matter, was that
- 7 they focused on consistency of supply, pricing and
- 8 quality of the products.
- 9 Q. Okay. Thank you. And turning to
- 10 Paragraph 182 -- sorry, 181, but just above still on
- 11 page 151.
- 12 A. Okay.
- 13 Q. Although we can read the sentence from the
- beginning, just go back to page 150. The sentence
- starting: "From a marketing and business
- 16 perspective, for each generic manufacturer who
- decided to enter the opioid market, the profit
- potential outweighed any barriers or potential
- 19 negative aspects of market entry, including concerns
- over the risks of selling opioids."
- 21 Did I read that correctly?
- 22 A. You did.
- 23 O. And this calculus, that profits outweigh the
- risks and costs of a particular product, that
- calculus is not unique to a decision to enter a

- 1 market for opioids; is that correct?
- 2 A. Yes, that's true, the go/no go decision
- described in this section on my report, it would be
- 4 true for any generic product being considered.
- 5 Q. Okay. And medications that are available by
- 6 prescription, as opposed to, say, over the counter,
- 7 that is because there is some degree of risks
- 8 associated with those medications, correct?
- 9 A. I think by definition, prescription
- 10 medications are more dangerous or more -- have more
- 11 potential for harms than over-the-continuer
- 12 medicines, yes.
- 13 Q. Okay. So a pharmaceutical manufacturer is
- 14 going to undergo a similar calculus when deciding to
- manufacture or enter the market for any drug,
- 16 correct?
- 17 A. I think there would be a contemplative
- decision that would be made and they would -- they'd
- 19 have criteria. Certainly I think the criteria for a
- branded product may be different and certainly have
- 21 higher implications in terms of the amount of
- investment that you've got to put into the product,
- the amount of time that it would take to develop and
- bring to market, but the overall "should we do this
- or not" is going to be pretty similar at the end of

- 1 the day: Is this a market where we can find enough
- 2 customers to satisfy a model that's going to
- generate the revenues we need to make to maximize
- 4 shareholder wealth and stay in business?
- 5 Q. Okay. And you're not giving an opinion that
- 6 there is anything wrong with selling generic opioid
- 7 medications; is that correct?
- 8 A. No, I'm not giving an opinion that there is
- 9 anything wrong with that.
- 10 Q. You're not giving an opinion that any
- 11 generic manufacturers in this case engaged in some
- wrongful act; is that correct?
- MR. CHALOS: Object to the form.
- 14 A. To the extent that, you know, opioid --
- 15 generic opioid manufacturers are part of the opinion
- 16 that, you know, the marketing expanded the opioid
- market, they would be implicated in that, I think,
- but I'm not making the assessment of right or wrong,
- only that the marketing resulted in this expansion.
- 20 So I think the answer to your question is no, I'm
- 21 not giving that opinion, but there are opinions that
- 22 are related to that in the report just about the
- expansion of the market, and certainly generics did
- have a role in the expansion of the market.
- Q. Okay. And generic opioids are subject to

- 1 DEA quotas; is that correct?
- 2 A. Yes.
- 3 Q. So --
- 4 A. As far as I know, yes.
- 5 Q. Okay. So manufacturers cannot simply
- 6 manufacture as much product as they want, correct?
- 7 A. That's my understanding how the opioid quota
- 8 system works, yes.
- 9 Q. Okay. And are you familiar with the duty of
- sameness when it comes to generic prescription
- 11 medicines?
- 12 A. I don't know if I've heard that exact
- phrase, but the -- I'm familiar with the
- 14 requirements for a generic are.
- 15 Q. Okay. And can you explain those
- requirements to me, in your understanding?
- 17 A. Right. So a generic can come to market
- without doing the clinical testing that the brand
- name product has to do, but the generic must be
- 20 bioequivalent and it must have the same
- 21 bioavailability. In other words, there is a -- I
- 22 think it used to be 85/120 rule, that the drug must
- be within certain parameters. So as long as the
- 24 drug is within those parameters of bioavailability
- and bioequivalence, that it's essentially the same

- 1 as the branded product.
- Q. And it's required to have the same label as
- 3 the branded product?
- 4 A. Yes, that's part of it as well. I was
- 5 taking it from a little bit different angle, but --
- 6 so -- but the indications, the safety information,
- 7 would all be exactly the same.
- Q. Okay. If we could turn to Paragraph 128.
- 9 A. Okay.
- 10 Q. And if -- if you look at that paragraph and
- 11 Footnote 253 cited in Paragraph 128, you're citing
- to the Boyer Teva deposition; is that correct?
- 13 A. Yes.
- 14 Q. And I believe you testified earlier that
- this was not one of the depositions that you read in
- its entirety; is that correct?
- 17 A. Yes, that's correct.
- 18 Q. Okay. And the first sentence reads:
- 19 "Mr. Boyer, former President and CEO of Teva,
- 20 testified that using sales representatives to
- 21 communicate with doctors about the proper use and
- 22 risks of opioids was cost prohibitive and not done
- 23 by Teva."
- 24 Did I read that correctly?
- 25 A. Yes, you did.

- 1 Q. This testimony relates to Teva's generic
- business; is that correct?
- A. Yes, generally speaking, yes.
- 4 Q. Do you recall from reviewing the deposition
- 5 transcript whether this was specific to Teva's
- 6 generic business?
- 7 A. As I recall, it was, yes.
- 8 Q. Okay. And is it your opinion, then, that
- generic manufacturers failed to warn about the risks
- of their generic opioid medications by failing to
- 11 use sales representatives to communicate with
- 12 doctors?
- A. No, I don't think that's my opinion
- 14 exactly.. I think that this was -- this was just
- 15 to -- again, you know, a case study analysis, you
- have to look at so many different data points and
- one of the data points that I was concerned about
- was the balance of information in terms of whether
- or not the -- you know, we spent a lot of time going
- through a lot of package inserts earlier today, and
- 21 certainly those package inserts have warnings in
- them and that's important. That has to be
- 23 considered.
- 24 But then if you -- if you have a product and
- it was simply a way of assessing whether or not, for

- 1 Teva's generic products, whether there was any
- 2 effort on the parts of sales, which there are a lot
- of sales reps out there bringing share of voice way
- 4 up for opioids, were there any sales reps out there
- 5 promoting the -- or communicating with doctors about
- the proper use of the generic opioids? So it was
- 7 just -- it's just a data point.
- 8 It's not really -- I mean, I don't really
- 9 even consider this judgmental against Teva. It's
- just simply that when we look at the overall balance
- 11 for generics, we generally aren't going to see a lot
- of personal selling and we're not going to see a lot
- of personal selling related to the risks or possible
- harms of opioids. It's just an artifact of the
- market. Again, it's not judgmental, it's just this
- is the state of where we are, this is what's
- 17 typically done in that marketing.
- 18 Q. What do you understand the public policy
- 19 reasons for making generic medications available in
- the market to be?
- 21 A. I think I address, to a certain extent, I
- 22 address that in the last section that we -- around
- Paragraph 180, where we just were. Generics
- 24 provide -- and we can certainly flip to that, but
- just in general, generics provide a lower cost

- 1 alternative that enables, from a couple of
- 2 perspectives, access to medications to be increased.
- On the one hand we have third-party payers
- 4 who have a preference towards generics because they
- 5 are cheaper and it makes it a better deal for their
- 6 insurers and for their pharmacy benefit managers and
- 7 eventually for the patients as well.
- For cash payments, generics present a lower
- 9 cost alternative that they may be able to afford
- when indeed they can't afford a brand name product.
- 11 So public policy-wise I see generics as a positive
- 12 thing.
- Q. And if generic manufacturers were using
- sales representatives to put out that voice, that
- would affect their ability to offer those low
- 16 prices; is that correct?
- 17 A. I mean, I don't -- I don't know the inner
- workings of the generic manufacturers and what it
- 19 would cost them to do that if they already have a
- sales force or if they don't. The ins and outs of
- that, my guess is it would cost them more money but
- I haven't undertaken that analysis and certainly
- don't know specifically for Teva, or any of the
- 24 manufacturers, if they could or couldn't, would or
- wouldn't, and what it would cost, so -- but with

- 1 that as a -- as sort of a caveat, I think certainly
- the conclusion could be drawn that if generics
- 3 started marketing exactly the way brand name
- 4 products did, they would cost more.
- Q. Okay. Thank you. Let's turn to Paragraph
- 6 137. The first sentence there reads: "Fears were
- 7 also minimized through marketing communications that
- 8 indicated problems like addiction occur only when
- 9 opioids are abused or used illegally."
- 10 And then there is a Footnote 275. Is that
- 11 correct?
- 12 A. Yes.
- Q. Okay. And if we look at 275 Footnote, it
- 14 starts: "See generally, e.g."
- And e.g. there means "for example," correct?
- 16 A. Uh-huh.
- 17 Q. So what follows is going to be an example to
- support that first clause of Paragraph 137; is that
- 19 correct?
- 20 A. Yes.
- Q. Okay. So if we read after the e.g. in
- Footnote 275, it says: "Proper assessment of
- patients, proper prescribing practices, periodic
- reevaluation of therapy, and proper dispensing and
- storage are appropriate measures to help limit abuse

- of opioid drugs."
- 2 Did I read that correctly?
- 3 A. Yes.
- 4 Q. So the quoted passage is about means to
- 5 limit abuse, correct?
- 6 MR. CHALOS: Object to the form.
- 7 A. The quoted passage does, yes.
- 8 Q. Okay. And do you agree that the things
- 9 listed in the quoted passage can be done to limit
- 10 abuse?
- 11 A. Yes. I think we would need to look at this
- whole document, though, to get the reason why that's
- being cited at 275, yeah.
- Q. Okay. And the quoted passage at least does
- not specifically mention addiction, is that correct?
- 16 A. Well, it doesn't mention addiction. It
- mentions abuse, so, yeah. Yeah.
- 18 Q. Okay. And it does not mention illegal use,
- 19 correct?
- 20 A. Right.
- Q. Okay. So I'm going to mark the document as
- 22 Exhibit 22.
- 23 (Perri Exhibit 22 was marked for
- identification.)
- 25 BY MS. COATES:

- 1 Q. I'll give you that copy.
- 2 A. Good throw.
- 3 Q. That one is not going to make it quite as
- 4 far.
- 5 All right. And that quote references
- 6 Page 11, right? And just for comparison, the Bates
- 7 Number is TEVA CHI 00000509. And that's the same
- 8 Bates Number on the document that I gave you,
- 9 correct?
- 10 A. Yes.
- 11 Q. Okay. And so if we turn to Page 11, and if
- 12 you look at the second bullet point, it says: "All
- patients treated with opioids require careful
- 14 monitoring for signs of abuse and addiction, since
- use of opioid analgesic products carry the risk of
- 16 addiction even under appropriate medical use."
- 17 Did I read that correct?
- 18 A. Yes.
- 19 Q. So this is acknowledging that addiction can
- occur when appropriately prescribed, correct?
- 21 A. Yes.
- Q. And it does not actually state anything
- about addiction occurring only when abused or used
- 24 illegally, correct?
- MR. CHALOS: Object to the form.

- 1 A. I'm finding myself wanting to look at this
- whole area so I can make sure.
- Q. Please.
- 4 A. I'm still trying to figure out if the
- 5 citation, you know -- why this was cited in this
- 6 particular occasion.
- 7 Q. Okay. Go ahead.
- 8 A. Thanks. Okay. Now, if you don't mind,
- 9 would you ask me your question?
- 10 Q. Sure. So I'm struggling to see anything on
- 11 Page 11 that's stating that addiction occurs only
- when abused or used illegally, which is the
- proposition that you cited this document as an
- 14 example of. Is that correct or --
- MR. CHALOS: Object to the form.
- 16 A. So this section of the report, and this
- 17 particular -- this Paragraph 137, one of my -- one
- of my contentions is that the marketing messages
- 19 minimized concerns over addiction -- dependence,
- tolerance, addiction, withdrawal. So the -- in this
- 21 sales training, which the topic of this page is
- "Abuse, Addiction & Diversion," so this is a
- 23 question-and-answer that is designed to -- if you
- look at the very first page of this document, it's
- teaching a way -- a selling technique to minimize

- concerns and focus on the product's benefits and
- features, and the reasons why it's okay to use the
- project -- product, basically.
- 4 So I agree with you, this is not a -- the
- best example I probably could have cited here, but
- it does meet the criteria of what I would say, that
- 7 it's a communication, that's training in the sales
- 8 force, designed to alleviate fears about abuse, and
- 9 the question-and-answer, it does a job of taking the
- doctor's fear, taking the prescriber's fear, and
- 11 reducing or minimizing that concern so that there
- will be less trepidation about using the product.
- Q. Okay. Thank you. Do you know what branded
- 14 products -- branded opioid products in particular
- 15 Teva or Cephalon manufactures?
- 16 A. Yes.
- Q. What are those products?
- 18 A. I believe Fentora and Actiq, and the new one
- 19 that's eluding me right now, the newer one. I'm --
- I'm drawing a blank on the name of the newer
- 21 product, so --
- Q. I'm not aware of any new product, so I can't
- 23 help you there.
- A. Well, Hang on just one second because I'm
- 25 thinking of something. So Fentora and Actiq I know

- for sure, and it may have been a competitor's
- 2 product but I thought there was another transmucosal
- or transbuccal immediate release fentanyl. Give me
- 4 just a second.
- It strikes me this is the first time in this
- 6 entire process that anybody has asked me about drug
- 7 names. It takes me a minute to adjust.
- 8 Q. Sure.
- 9 A. Ah, okay. It was -- it says here Subsys.
- 10 That's it. I'm good.
- 11 Q. That's correct. Thank you.
- Okay. And you testified earlier that you're
- relying on other experts to determine whether any
- branded marketing by Teva or Cephalon was false or
- misleading; is that correct?
- 16 A. The assessment of the specific messages and
- their false and misleading, incorrect, whatever,
- 18 yes, I'm relying on other experts for that.
- 19 Q. And are you familiar with the TIRF REMS
- 20 Access program?
- 21 A. I'm generally familiar with it as I am all
- the different REMS -- well, there weren't a lot of
- different REMS but there were a couple of different
- 24 REMS that were involved here, so I'm generally
- familiar with the requirement of that REM, yes.

- Q. And are you aware that since 2012, Actiq and
- 2 Fentora have been subject to the TIRF REMS Access
- 3 program?
- 4 A. I don't know the exact date of when that
- 5 happened but I think that's about the right time
- 6 period as I have it in my mind.
- 7 Q. Okay. Do you know what the prescriber
- 8 requirements of the TIRF REMS Access program are?
- 9 A. I -- as I recall, they are very similar to
- the other opioid REMS and it's requiring prescriber
- 11 training and education and a few other features I
- don't recall specifically.
- Q. Do you know if there is a reason that TIRF
- 14 products have their own specific REMS?
- 15 A. Yes, because of the difference in
- administration and the potential for problems to
- occur if they are not used properly.
- 18 Q. And so being subject to their own specific
- 19 TIRF REMS, presumably those TIRF REMS have different
- 20 requirements or additional requirements to the other
- 21 REMS?
- 22 A. They're different, yes. Again, I don't
- recall exactly the details in the REMS, but I am
- 24 familiar that it's -- that exists and that it was --
- as I recall, it was slightly different, but at the

- 1 same time similar to the others.
- 2 (Perri Exhibit 23 was marked for
- 3 identification.)
- 4 BY MS. COATES:
- 5 Q. Okay. I'm going to hand you what I'm going
- 6 to mark as Exhibit 23.
- 7 A. Thanks. Good job.
- Q. That one slides. This one is harder.
- 9 MR. CHALOS: That was a good one.
- MS. COATES: Thank you.
- 11 Q. Do you recognize this document?
- 12 A. I recognize it as the Actiq package insert
- from 2011 era. It was complete prescribing
- information, I should say. Oh, there is a med quide
- 15 here as well.
- Q. And do you see the date on this package
- insert anywhere?
- 18 A. December 2011.
- 19 Q. Okay. And so as I think we discussed, this
- would be just before the TIRF REMS program was
- implemented, but if we turn to the fourth page in
- 22 Section 5.10 --
- 23 A. Yes.
- Q. -- it discusses what the requirements of the
- 25 TIRF REMS Access program are going to be in

- 1 Section 5.10 titled "Transmucosal Immediate Release
- 2 Fentanyl (TIRF) Risk Evaluation and Mitigation
- 3 Strategy (REMS) Access Program."
- 4 Did I read that correctly?
- 5 A. You did.
- Q. And if you look underneath the first full
- 7 paragraph there, it goes through the required
- 8 components of the TIRF REMS Access program.
- 9 A. Yes.
- 10 Q. And so the first requirement is that:
- 11 "Healthcare professionals, who prescribe Actiq for
- outpatient use, must review the prescriber
- educational materials for the TIRF REMS Access
- program, enroll in the program, and comply with the
- 15 REMS requirements."
- 16 Did I read that correct?
- 17 A. You did.
- 18 Q. And the second bullet: "To receive Actiq,
- outpatients must understand the risks and benefits
- and sign a Patient-Prescriber Agreement."
- 21 Did I read that correct?
- 22 A. You did.
- Q. And "Pharmacies that dispense Actiq must
- enroll in the program, and agree to comply with the
- 25 REMS requirements."

- 1 Did I read that correct?
- 2 A. Yes.
- Q. And "Wholesalers and distributors that
- 4 distribute Actiq must enroll in the program, and
- distribute only to authorized pharmacies."
- Is that correct?
- 7 A. Yes.
- 8 Q. So these are requirements that are specific
- 9 to this class of medications; is that correct?
- 10 A. Well, these requirements are -- yes, I
- agree, they are specific to Actiq and this class of
- drugs. They are not unique in terms of REMS. There
- are other programs that pharmacists and doctors have
- to enroll and so forth, but this is certainly unique
- to the other opioids.
- 16 Q. Okay. Thank you. And I'm not going to go
- 17 through multiple iterations of labels with you, but
- I do just want to confirm that there is a boxed
- warning or a black box warning, however you want to
- 20 refer to it --
- 21 A. Yes.
- 22 Q. -- applicable to these medications as well.
- 23 A. There is.
- Q. Okay. Can we turn to Table II of your
- report? I believe it starts on page 86. And as

- we've discussed, Table II is sort of your
- 2 categorization of the marketing messages that you
- 3 reviewed; is that correct?
- 4 A. Yes.
- Q. And as we discussed, these are not typically
- 6 the type of marketing messages that generic
- 7 manufacturers are going to be communicating, that
- 8 these marketing messages would be more related to
- 9 branded manufacturers; is that correct?
- 10 A. Yes, essentially, that's correct.
- 11 Q. Okay. And Section A, your first marketing
- message: Extended release drugs or q12 dosing had
- fewer peaks and valleys and less chance of addiction
- 14 and abuse.
- 15 Is that correct?
- 16 A. Yes.
- 17 Q. And I guess I should have asked you this
- 18 previously, but Actiq or Fentora are not extended
- use drugs, is that correct, extended release drugs?
- 20 A. They are not used in this fashion, no.
- Q. Okay. And there are no Teva documents
- listed in this section; is that correct?
- A. No, there are not.
- MS. COATES: Okay, Doctor. I think that I
- am done with my questions, I tried to be short

- and sweet, and I think we can now take a break.
- THE VIDEOGRAPHER: We are now going off the
- record. The time is currently 2:20 p.m.
- 4 (Recess from 2:20 p.m. until 2:36?p.m.)
- 5 THE VIDEOGRAPHER: We are now back on the
- 6 video record with the beginning of Media
- 7 Number 5. The time is currently 2:36 p.m.
- 8 CROSS-EXAMINATION
- 9 BY MS. ZOLNER:
- 10 Q. Good afternoon, Dr. Perri. My name is Erica
- 11 Zolner. I've been sitting on this side of the room,
- 12 so I'm not sure we've seen each other much in the
- last couple of days, but I represent Allergan
- 14 Finance and I'm going to be asking you some
- 15 questions specifically about my client.
- 16 A. Okay.
- 17 Q. And just to be clear, although I think there
- have been many people asking you these questions,
- 19 you are not offering any Allergan-specific opinions,
- 20 correct?
- MR. CHALOS: Object to the form.
- 22 A. Yes, that's correct.
- Q. And you're also not offering any
- 24 Actavis-specific opinions, right?
- MR. CHALOS: Object to the form.

- 1 A. Yes, that's correct.
- Q. Let's turn to your report.
- 3 A. Okay.
- 4 Q. And I think you already have a copy which
- was previously marked Exhibit 1.
- 6 A. Yes.
- 7 Q. Could you look at Paragraph 174?
- 8 A. Okay.
- 9 Q. In that paragraph you state that Actavis
- 10 marketed an opioid medication called Kadian,
- 11 correct?
- 12 A. Yes.
- 13 Q. Are you aware that Actavis acquired Kadian
- 14 from a company called Alpharma?
- 15 A. I believe that's correct, yes.
- 16 Q. Do you know when Actavis acquired Kadian
- 17 from Alpharma?
- 18 A. I don't have an exact date, no.
- 19 Q. Okay. And I'm not expecting it to be a
- 20 memory test. I'll represent to you that it was in
- December of 2008. Do you have any reason to
- 22 disagree with that date?
- 23 A. No, that seems about what I -- that seems
- about right to me.
- Q. Does your report cite marketing statements

- 1 by Alpharma?
- 2 A. With respect to the family of companies
- 3 related to Actavis, I'm pretty sure they are all
- 4 referenced as -- let me took at Table II just to be
- 5 sure.
- Q. While you are looking at that, you're not
- 7 suggesting that Alpharma is part of the Actavis
- 8 or Allergan family of companies,
- 9 A. Say that again.
- 10 Q. Sure. You're not suggesting that Alpharma
- is part of the Allergan or Actavis family of
- 12 companies?
- 13 A. Okay. So your question was specific to
- 14 Alpharma?
- 15 Q. That's right.
- 16 A. Yeah. So I know that Alpharma is not cited
- in Table II or anywhere, yes.
- 18 Q. Okay.
- 19 A. So yes.
- Q. Could you look at Page 93 of your report?
- 21 A. Okay.
- Q. At the bottom of that page you quote a
- document stating: "Over time, your body may become
- tolerant of your current dose. You may require a
- dose adjustment to get the right amount of pain

- 1 relief. This is not addiction. It is just your
- body getting used to the drug."
- 3 Did I read that correctly?
- 4 A. Yes.
- 5 Q. You attribute that statement to Allergan,
- 6 right?
- 7 A. That's what I was going to say a little bit
- 8 earlier, is that all of -- anything that has to do
- 9 with this family of defendants is -- Actavis and
- 10 Allergan, would be listed as Allergan.
- 11 Q. I guess I'm confused by what you mean by
- "family of defendants."
- 13 A. With all the mergers --
- MR. CHALOS: Sorry. Let her finish her
- 15 question, if you would. Sorry. You can answer.
- 16 Q. Thank you. We talked earlier about the fact
- that Actavis acquired Kadian, the branded drug, from
- 18 Alpharma in December 2008, right?
- 19 A. We did talk about that.
- 20 Q. And you understand that Actavis did not
- 21 acquire Alpharma, right?
- 22 A. Yes.
- Q. Okay. So maybe you can describe to me what
- you mean when you keep saying that there is a family
- of defendants?

- 1 MR. CHALOS: Object to the form.
- 2 A. So in my report I have a tab for Schedule 6
- 3 that is the ARCOS Opioid Drugs and Defendant
- 4 Corporate Groupings, and among other things it lists
- 5 the name of a drug, the status of that drug, who the
- 6 defendant is, and then manufacturers of that, and
- 7 the -- so I was careful in this table to list only
- 8 companies that are listed as a defendant, whether
- 9 they were --
- So, for example, with the product fentanyl,
- 11 I'm looking at Table 1 in this Exhibit 6. For
- 12 fentanyl, the defendant includes Actavis, Endo,
- 13 Mallinckrodt and Teva, and under the Actavis tab,
- 14 Actavis and Watson are both listed. So I -- that's
- what I'm referring to as the corporate families or
- 16 groupings of defendants.
- 17 Q. Okay. But let's try to break that down. Do
- 18 you understand that Alpharma is not a defendant in
- 19 this litigation?
- 20 A. Yes, I have -- I can check on that, too.
- 21 Let me see.
- Schedule 5 is the list of the defendants in
- 23 the case --
- Q. Right. And you've listed them in
- 25 alphabetical order, right?

- 1 A. Right.
- Q. And I do not see Alpharma listed there?
- 3 A. That's correct.
- Q. Okay. So Alpharma is not part of the family
- of defendants in this litigation, correct?
- 6 A. Did I say that they were?
- 7 Q. I'm confused by your term "family of
- 8 defendants" because defendants have specific meaning
- 9 in the context of litigation.
- 10 A. Okay.
- 11 Q. So maybe let's just take one step back.
- 12 A. Okay.
- 13 Q. Isn't it correct that Alpharma is not part
- of this lawsuit?
- 15 A. That's my understanding, yes.
- Q. And it's also your understanding that
- 17 Alpharma is not part of the family of defendants
- that's part of the Allergan umbrella, correct?
- MR. CHALOS: Object to the form.
- 20 A. I assume so. The comings and goings of the
- 21 different companies, the mergers, acquisitions,
- licensing, purchasing of products, I looked at the
- products themselves and their marketing. I didn't
- 24 really focus extensively on the -- you know, who was
- 25 making it when. It was when did a product come to

- 1 market, what was the marketing planning, what was
- the metrics that were used to evaluate it, what
- 3 tactics were used, what strategies were used.
- 4 Q. Got it. But you were looking at the
- 5 question of when a product came to market?
- 6 A. Right.
- 7 Q. I think that's what you just testified to.
- 8 And you were also including dates in the documents
- 9 that you cited throughout your report, correct?
- 10 A. Wherever possible, yes.
- 11 Q. So let's take a look at a document that I'm
- 12 going to mark Exhibit 24.
- 13 (Perri Exhibit 24 was marked for
- 14 identification.)
- MS. ZOLNER: This table is so long.
- MR. CHALOS: Do you have another copy of
- 17 that?
- MS. ZOLNER: I'll try to shuffle it across.
- 19 (Discussion off the record.)
- 20 BY MS. ZOLNER:
- Q. Dr. Perri, if you could just look at the
- first page in the upper left-hand corner, do you see
- there where it's marked "Kadian"?
- A. I'm confused. Upper left-hand corner?
- Q. Upper right-hand corner. My apologies.

- 1 A. Thank you. Yes.
- Q. And then under that it says: "Learn more
- 3 about customized pain control with Kadian."
- 4 A. Yes.
- 5 Q. And then you quote from language in your
- 6 report on the fourth page of this PDF, correct? And
- 7 just for clarification, that's the page that's
- 8 marked ACTAVIS0006826, and I believe in your report
- 9 on page 93, which was the portion of your report we
- were looking at before I showed you Exhibit 24, we
- were looking at that language that I quoted earlier.
- 12 A. Okay.
- 13 Q. The "over time, your body..." section.
- 14 A. Yes.
- 15 Q. Do you recall that?
- 16 A. Yes.
- 17 Q. Do you see that language quoted on Page 4 of
- 18 Exhibit 24?
- 19 A. Yes.
- Q. If you turn to the last page of Exhibit 24,
- 21 do you see in the bottom right -- bottom left-hand
- corner there is a copyright date, and it's copyright
- 23 2007, Alpharma Branded Products Division?
- 24 A. Okay.
- Q. Do you see that?

- 1 A. I do.
- Q. And then do you see that the document is
- also dated in the next line March 2007?
- 4 A. Okay.
- 5 Q. And you'll recall several questions ago I
- 6 represented to you that Actavis acquired Kadian in
- 7 December of 2008. Do you remember that?
- 8 A. You did.
- 9 Q. So that was over a year before -- this
- document was published over a year before Actavis
- 11 acquired Kadian, correct?
- 12 A. That's right.
- MR. CHALOS: Hold on. Object to the form.
- Q. Do you have any reason to believe that
- 15 Actavis ever used this document after it acquired
- 16 Kadian?
- 17 A. I don't have any reason to suspect that they
- 18 did or didn't. I wouldn't know.
- 19 Q. What about Allergan, do you have any reason
- to suspect Allergan ever used this document?
- 21 A. I wouldn't know based on this document.
- Q. Did you do any research to determine when
- 23 Actavis acquired Kadian from Alpharma prior to your
- 24 deposition today?
- 25 A. You know, that's -- I appreciate the

- 1 question and the answer, I think, is no but maybe.
- I was concerned with the marketing of Kadian. I
- wasn't concerned with who made it, when they made
- 4 it, and I wanted to see the marketing for Kadian and
- 5 that's what I focused on.
- 6 That's why I don't have independent opinions
- 7 about each individual defendant or another. The --
- 8 what I was focused on was the marketing of opioids.
- 9 So whether Kadian was owned by you or someone else,
- 10 I wanted to know what was happening with Kadian and
- 11 that's what I stayed with.
- 12 Q. Understood. And you weren't paying
- attention to ownership lines or who was responsible
- 14 for manufacturing the drug in your review of the
- 15 marketing materials?
- 16 A. I tried to pay attention to that, but it was
- impossible to keep that straight at all points for
- 18 every drug at every point in time because there were
- 19 so many mergers, acquisitions, licensing and so
- 20 forth that -- I did the best that I could, I think,
- in keeping track of where everybody was with respect
- to ownership and all that.
- 23 And I know certainly from reading some of
- the depositions, and particularly with regard to
- 25 Allergan Financial, that there was a lot of question

- about ownership and things like this, so I
- 2 appreciate your concern over this and I'm sure you
- all will figure out an answer to that, but from my
- 4 perspective, this was about Kadian, not about who
- 5 owned it at that time.
- 6 Q. Understood. So just for points of
- 7 clarification, as you sit here today you can't
- 8 recall any specific research you did to determine
- 9 when Actavis acquired Kadian from Alpharma?
- 10 A. Not other than what I would have read in the
- deposition transcripts about the timing of when
- things happened, yeah.
- Q. Could you turn to Page 96 of your report
- 14 now?
- 15 A. Okay.
- Q. Do you see where you wrote -- and this is by
- the Actavis document in your chart, 0006930, do you
- 18 see that?
- 19 A. Yes.
- Q. "It is important for these audiences to
- 21 understand the difference between addiction and
- 22 pseudoaddiction, which involved medication-seeking
- behavior solely for the sake of pain relief. While
- 24 tolerance to opioids can occur, a dose increase of
- switch to another agent will often yield the needed

- 1 pain relief. Tolerance can also work advantageously
- for the patient, since it also applies to adverse
- 3 events."
- 4 Did I read that right?
- 5 A. You did.
- 6 Q. And you attribute that statement to
- 7 Allergan, right?
- 8 A. Yes, for the reason I explained earlier,
- 9 yes.
- 10 Q. And by "the reason I explained earlier," you
- mean that you weren't focused on the dates of
- ownership for any particular drug?
- 13 A. Not just that, but that is part of it.
- 14 The -- it's just Allergan as a named defendant. I
- wanted the column, this last column, to be a named
- 16 defendant, so whatever defendant family might have
- been there. So while it may have been an Actavis
- document, it's listed under Allergan as the
- 19 defendant.
- Q. Okay. Even though Allergan didn't own the
- 21 drug at the time, it's still listed under Allergan?
- A. Again, if that's the case, then that's like
- the last example. I wasn't focused enough on the
- 24 dates.
- 25 Q. Understood. The statement did come from

- 1 ACTAVIS0006930, that's the document you're quoting,
- 2 right?
- A. You know, I've looked at all of these
- 4 documents, so I know that it came from that
- document, but I can't tell you the time frame of it,
- 6 so --
- 7 Q. Understood. Why don't -- why don't we mark
- 8 that document.
- 9 A. Okay.
- 10 Q. Let's mark it Exhibit 25.
- 11 (Perri Exhibit 25 was marked for
- 12 identification.)
- 13 BY MS. ZOLNER:
- 14 A. Good job.
- Q. We should bring a carrier pigeon.
- I think the good news here is we're just
- 17 going to look at the first page.
- 18 A. Okay.
- 19 Q. So do you see where it says in the middle of
- the page, "Kadian 2005 Publication Plan"?
- 21 A. Yes.
- Q. It also says this document was prepared by
- 23 Alpharma on January 20th, 2005. Do you see that?
- 24 A. I do.
- Q. Do you have any reason to disagree with

- what's written on the first page of Exhibit 25?
- 2 A. No, I do not.
- Q. As you sit here today, do you know if
- 4 Actavis ever used this document?
- 5 A. What I was undertaking here was to look at
- the contents specifically to refresh my memory about
- 7 what may have been going on in this planning
- 8 document, and then my thought was to get ahold of an
- 9 Actavis document, Actavis marketing plan for Kadian
- and then compare them and see, and then maybe draw
- 11 the conclusion that they are similar or they're not
- very similar and I could possibly answer your
- question, but since I don't have the second
- 14 document, I can't really do that.
- 15 Q. My question was a simple one. I just was
- asking do you know if this document was ever used by
- 17 Actavis?
- 18 A. As I sit right now, I don't know.
- 19 Q. Okay. What about Allergan, as you sit here
- 20 now do you know if this document was ever used by
- 21 Allergan?
- 22 A. I do not know that.
- Q. And I'm speaking about Exhibit 25, just for
- 24 the record.
- 25 A. Right.

- Q. In the case of Actavis, are you aware of any
- 2 regulatory or administrative action by the FDA?
- MR. CHALOS: Object to the form.
- 4 A. I don't recall as I sit here.
- 5 Q. What about Allergan, are you aware of any
- further regulatory or administrative action by the
- 7 FDA against Allergan?
- 8 MR. CHALOS: Object to the form.
- 9 A. Again, as I sit here, I don't recall.
- 10 Q. Let's go back to your report and I'm looking
- 11 at Paragraph 137 now. Let me know when you're
- 12 there.
- 13 A. 127?
- 14 Q. 137.
- 15 A. Okay.
- Q. Paragraph 137.
- 17 A. I'm there. I'm there.
- 18 Q. Okay. You state here that: "Fears were
- 19 also minimized through marketing communications that
- indicated problems like addiction occur only when
- opioids are abused or used illegally, and if opioids
- are taken as prescribed, the risk of addiction is
- rare, less than 1 percent."
- 24 Did I read that correctly?
- 25 A. Yes.

- 1 Q. Looking at your support materials, I want to
- 2 start with Footnote 276, and there you're citing a
- document which is ACTAVIS0264972.
- 4 Do you see that?
- 5 A. Yes.
- 6 Q. Okay. And in that footnote, Footnote 276,
- 7 it says: "See generally, e.g. 'long history of
- 8 safety and efficacy when used as indicated' Kadian
- 9 Marketing Overview, ACTAVIS0264972, page 31."
- 10 Did I read that right?
- 11 A. Yes.
- 12 Q. And as you note in your footnote, the
- document states that for Kadian, there is a long
- 14 history of safety and efficacy when used as
- 15 indicated, right?
- 16 A. Yes.
- 17 Q. I'd like to now mark Exhibit Number 27 --
- 18 26. I'm sorry.
- 19 (Perri Exhibit 26 was marked for
- 20 identification.)
- 21 BY MS. ZOLNER:
- Q. And again, this is -- the document that we
- have just marked Exhibit 26 is a Kadian Marketing
- 24 Overview from Sales Representative Training on
- October of 2011. Do you see that?

- 1 A. Yes.
- Q. Could you look at Page 31? It's the page
- 3 that says "Efficacy" at the top.
- 4 A. Yes.
- 5 Q. The very first bullet on Page 31 of
- 6 Exhibit 26 says: "Kadian contains morphine as its
- 7 active ingredient and has a long history of safety
- 8 and efficacy when used as indicated."
- 9 Did I read that correctly?
- 10 A. Yes.
- 11 Q. Again, I know you've testified repeatedly
- that you're not here to offer FDA expertise, but I
- have a question on this.
- 14 Are you aware that before the FDA approves a
- drug for marketing, it must first determine if a
- 16 drug is effective?
- 17 A. Safe and effective, yes, safe and effective,
- 18 yes.
- 19 Q. Okay. And are you also aware that the FDA
- is responsible for making sure that the benefits
- outweigh its potential risks to patients?
- MR. CHALOS: Object to the form.
- Q. Let me rephrase that.
- One of the other issues that the FDA is
- considering before approving a drug for marketing is

- whether the benefits outweigh potential risks to
- patients, correct?
- 3 A. That's my understanding of what the FDA's
- 4 goal is.
- 5 Q. Let's look now at Exhibit 27.
- 6 (Perri Exhibit 27 was marked for
- 7 identification.)
- 8 BY MS. ZOLNER:
- 9 Q. Thank you. This, Dr. Perri, is -- the
- document that we just marked Exhibit 27 is the FDA
- 11 approval letter for Kadian that came in on July the
- 12 3rd, 1996, correct?
- 13 A. Yes.
- Q. And the first paragraph of this letter
- written to Mr. Wagner is: Please refer to your June
- 16 29, 1995 new drug application, or NDA, submitted
- under Section 505(b) of the Federal Food, Drug, and
- 18 Cosmetic Act for Kadian (morphine sulfate) Sustained
- 19 Released Capsules, 20 milligrams, 50 milligrams and
- 20 100 milligrams.
- 21 Did I read that correctly?
- 22 A. Yes.
- Q. If you look down to the fourth paragraph,
- 24 this explains that in approving Kadian, the FDA
- 25 concluded that Kadian was safe and effective for the

- use as indicated, correct?
- 2 A. Yes.
- Q. Are you aware if the FDA ever requested that
- 4 Kadian be removed from the market?
- 5 A. I don't know.
- Q. Do you know if Kadian is still sold today?
- 7 A. I know that the generic forms pretty much
- 8 took over the marketplace for Kadian eventually, so
- 9 I don't know if it's still sold as a branded product
- or not.
- 11 Q. You just don't know one way or the other?
- 12 A. No.
- Q. Okay. Is it accurate to say that the
- statement, "Kadian has a long history of safety and
- efficacy when used as indicated," comes directly
- 16 from the FDA approval letter?
- MR. CHALOS: Object to the form.
- 18 Q. And again, I was looking specifically at
- 19 Paragraph 4.
- 20 A. Yes, I see that.
- MR. CHALOS: Object to the form.
- 22 A. I see that.
- Q. Is it accurate to say that that statement
- comes from Paragraph 4 of the FDA approval letter?
- MR. CHALOS: Object to the form.

- 1 A. Yes.
- Q. I'm sorry. I couldn't hear your answer.
- 3 A. Yes.
- 4 Q. Do you have any reason to dispute that the
- 5 language in the FDA approval letter is accurate?
- 6 MR. CHALOS: Object to the form.
- 7 A. I have no reason to dispute that.
- 8 Q. Could you go back to your report now,
- 9 please? Sorry to have you shuffle so many papers.
- 10 A. That's okay.
- 11 Q. I'm looking now at Footnote 275.
- 12 A. Okay.
- 13 Q. You cite a document, ACTAVIS0567695 in
- 14 Note 275, right?
- 15 A. Yes.
- 16 Q. And in that footnote you cite that document
- for the quote: "Opioid agonists are sought by drug
- abusers and people with addiction disorders and are
- 19 subject to criminal diversion. These risks should
- 20 be considered when prescribing or dispensing Kadian
- in situations where there is concern about increased
- risk of misuse, abuse, or diversion. Concerns about
- abuse, addiction, and diversion should not, however,
- 24 prevent the proper management of pain."
- 25 And that come from the Kadian PI Workshop

- with the Bates number ACTAVIS0567695, Page 17.
- Did I read that right?
- 3 A. Yes.
- 4 Q. So that cite is part of a document that was
- 5 entitled the Kadian PI Workshop?
- 6 A. Yes.
- 7 Q. Did you review that document?
- 8 A. Yes.
- 9 Q. Would you remind the jury what PI means? I
- 10 know you previously gave a definition, but just for
- 11 purposes of my recollection.
- 12 A. Well, it's either package insert or
- prescribing information, one or the other.
- Q. A pharmaceutical manufacturer's marketing
- claims must be consistent with PI; isn't that right?
- 16 A. Yes.
- 17 Q. In your report at Paragraph 89 --
- 18 A. Okay.
- 19 Q. -- you include a quote right after Footnote
- 20 166 that says: "This means marketers can be
- 21 selective in what they choose to talk about in a
- 22 sales encounter, but the information selected must
- 23 be consistent with the P.I."
- 24 Correct?
- 25 A. Yes.

```
Going back to Note 275, you state that
 1
        Ο.
     the --
 3
             MR. CHALOS: Hold on.
 4
             MS. ZOLNER: Sure.
 5
             MR. CHALOS: Okay.
 6
             MS. ZOLNER: Let me know when you're both
 7
        there.
 8
             MR. CHALOS: Oh, yeah. No, I'm sorry.
 9
             MS. ZOLNER: Okay.
10
             MR. CHALOS: It's more important that you're
11
        there.
12
             MS. ZOLNER: I'll wait for both of you.
13
        A. I'm there too, so --
14
        Q.
             Okay.
15
        Α.
             Yeah.
16
             At Note 275 you state that the Kadian PI
        Ο.
17
     Workshop makes the following claim, and this is I
18
     think the third sentence in -- well, it's more than
19
     the third sentence in that paragraph but it starts:
20
      "Concerns about abuse, addiction, and diversion
21
      should not, however, prevent the proper management
22
     of pain."
23
             Did I read that correctly?
24
        Α.
             Yes.
25
             MS. ZOLNER: Can we mark the PI Workshop,
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- the Kadian PI Workshop? It's Tab 15.
- 2 (Perri Exhibit 28 was marked for
- 3 identification.)
- 4 BY MS. ZOLNER:
- 5 Q. I will turn your attention to Page 17 of the
- document that we just marked Exhibit 28, Page 17.
- 7 A. Okay.
- Q. This is under the heading "Abuse Potential,"
- 9 and if you look at the third bullet, I think that's
- where we found the quote that we just found in your
- 11 report in Paragraph 137, Note 275. Again the
- 12 language is identical: "Concerns about abuse,
- addiction, and diversion should not, however,
- 14 prevent the proper management of pain."
- 15 A. Okay.
- 16 Q. That's the statement you cited, right, from
- the PI Workshop document?
- 18 A. Wrong page. Yes.
- 19 Q. And if you turn to the front of this
- document, the Kadian PI Workshop is dated March
- 21 2013. Do you see that?
- 22 A. I do.
- Q. Okay. Now I'm going to show you -- yes.
- I'm going to show you a different document. This is
- 25 Exhibit 29.

- 1 A. Should I be keeping all these documents open
- 2 or --
- Q. You can just put them in a pile. I don't
- 4 think we'll come back to any.
- 5 A. Okay.
- 6 (Perri Exhibit 29 was marked for
- 7 identification.)
- 8 MS. ZOLNER: We will come back to this one?
- 9 BY MS. ZOLNER:
- 10 Q. My colleague tells me you might want to put
- 11 this one to the side after we talk about it because
- we might talk about it twice.
- 13 A. Okay.
- Q. So this is Exhibit 29. Dr. Perri, if you
- will look in the bottom right-hand corner, do you
- see the revised date of July 2012?
- 17 A. Yes.
- 18 Q. Do you agree that this was the Kadian PI
- that was in effect in July of 2012?
- MR. CHALOS: Object to the form.
- 21 A. That looks like what that -- it looks as to
- be -- it looks like this is what that is, yes.
- Q. Okay. Could you turn to Page 6 of this
- document, and I don't know that the pages are
- 25 numbered.

- 1 A. Section?
- Q. I'm actually looking at the page -- Section
- 3 5, Warnings and Precautions.
- 4 Right. So it's Page 6 if you are counting
- 5 manually, and I am -- it's the reference ID in the
- 6 bottom -- I think, actually, all those numbers are
- 7 the same, but I am -- Section 5, Warnings and
- 8 Precautions, 5.1, Abuse Potential.
- 9 A. I'm there.
- 10 Q. Okay. Could you read the last sentence in
- 11 the first paragraph under that subpoint? It
- 12 starts --
- 13 A. "Concerns about abuse, addiction, and
- 14 diversion should not, however, prevent the proper
- management of pain."
- Q. Dr. Perri, would you agree that the sentence
- 17 you just read is identical to the sentence in the
- 18 FDA-approved prescribing information?
- 19 A. Yes, I would agree with that.
- MR. CHALOS: Object to the form.
- Q. In your report on Page 93 you cite this
- statement again, quoting a document called the
- 23 Kadian Stocking Offer, that's a document that is
- 24 again under the chart on Page 93, an Actavis --
- acquired Activis document marked 00369188. Just let

- 1 me know when you are there.
- 2 A. Okay. I'm there.
- 3 Q. That's the same sentence again, correct?
- 4 A. It is.
- 5 Q. "Concerns about abuse, addiction, and
- 6 diversion should not, however, prevent the proper
- 7 management of pain."
- 8 Is that sentence identical?
- 9 A. It is.
- 10 Q. Your report cites several statements found
- in the Kadian marketing and training materials that
- come directly from the Kadian PI, right?
- 13 A. That's correct.
- 14 Q. Let's look at Page 101 of your report where
- 15 you cite a July 2010 document. That one has a Bates
- 16 number of ALLERGAN MDL 00405512. Could you read me
- what you have in quotes by that document? And the
- date of that document is July 30th, 2010 in your
- 19 report.
- 20 A. "Proper assessment of the patient, proper
- 21 prescribing practices, periodic reevaluation of
- therapy and proper dispensing and storage are
- appropriate measures that help limit the abuse of
- 24 opioid drugs."
- Q. Do recall what that -- do you recall what

- document that language comes from?
- 2 A. I would have to see the document to make
- 3 sure, but -- I mean, I don't remember the specific
- 4 document.
- 5 Q. Okay. I'll show it to you. Let's mark this
- 6 Exhibit 30.
- 7 A. Oh, yeah.
- 8 (Perri Exhibit 30 was marked for
- 9 identification.)
- 10 BY MS. ZOLNER:
- 11 Q. This document is titled: Objection Handling
- Workshop, Training Class July 7th and 8th, 2010.
- 13 Correct.
- 14 A. Yes.
- 15 Q. In going back to your report, you explain in
- 16 Paragraph 135, Note 264 -- it's a footnote to
- 17 Paragraph 135, that: "Sales personnel were trained
- on how to handle objections to multiple issues,
- including concerns over addiction. See, e.g.,
- 20 Kadian objection handler ACTAVIS0003698."
- 21 And I think my question is a simple one. Is
- the Objection Handling Workshop document that we
- just marked Exhibit 30 the type of training
- 24 presentation that you're talking about in Paragraph
- 25 135?

- 1 MR. CHALOS: Object to the form.
- 2 A. Yes.
- 3 Q. Earlier in your report, on Paragraph --
- 4 under Paragraph 89 you have a Note 169 where you
- 5 explain that: "Handling objections and reducing
- 6 concerns prescribers may have about a medication is
- 7 a staple of sales training and development."
- 8 Let me know when you are there. I'm sorry.
- 9 I thought you were already on Paragraph 89. I'm
- 10 looking specifically at Note 169.
- 11 A. Yes, I'm there.
- 12 Q. Looking again at Exhibit 30, I'm just asking
- you to compare and contrast your report with what
- 14 I've marked as Exhibit 30, the Objection Handling
- Workshop. If you turn to Page 8 of this document,
- 16 Exhibit 30, you see the statement you cited about
- 17 proper assessment of the patient, right? And it's
- 18 the page that begins with -- says at the top:
- 19 "Objection 4. I'm concerned about the abuse
- 20 potential of Kadian."
- 21 A. Right.
- Q. Again, if you could just read that first
- 23 bullet.
- A. "Proper assessment of the patient, proper
- prescribing practices, periodic reevaluation of

- therapy, and proper dispensing and storage are
- 2 appropriate measures that help to limit abuse of
- opioid drugs."
- 4 Q. Okay. And I told you you were going to need
- 5 Exhibit 29 again. That was the one I said to keep
- 6 close at hand. If you look at page 15 of that
- 7 document, this is Section 9.2, it's titled "Abuse."
- 8 A. Okay.
- 9 Q. Could you please read the second full
- paragraph under 9.2?
- 11 A. "Drug abuse is the intentional and
- 12 nontherapeutic use -- "
- Q. Actually, I'm sorry, I don't want you to
- 14 read something that you don't need to read. That is
- 15 not the right section.
- Next page. Sorry about that. This is the
- second full paragraph at the top of the next page,
- right before you get to Section 9.3, Dependence.
- 19 A. "Proper assessment of the patient, proper
- 20 prescribing practices, periodic reevaluation of
- therapy, and proper dispensing and storage are
- 22 appropriate measures that help to reduce abuse of
- 23 opioids."
- Q. Do you agree that the statement that you
- cited from the Objection Handling Workshop,

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Exhibit 30, comes directly from the Kadian prescribing information that we marked as
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- 3 Exhibit 29?
- 4 A. Yes.
- 5 MR. CHALOS: Object to the form. I'm sorry.
- I lost you. Where did you say he -- I'm back
- on -- I may be a few questions behind. Where did
- 8 he cite that in his report?
- 9 MS. ZOLNER: Where did he cite what?
- MR. CHALOS: That sentence you just had him
- 11 read.
- MS. ZOLNER: The sentence that I just read
- was cited in his report in Paragraph 1 -- oh,
- 14 101.
- MR. CHALOS: Page 101?
- MR. CIULLO: Yes.
- 17 MR. CHALOS: Okay. Sorry. I'm just
- having -- you're moving quickly through your
- outline. I'm having trouble keeping up. Page
- 20 101.
- 21 BY MS. ZOLNER:
- Q. Dr. Perri, again, not to be repetitive, but
- can you identify a single specific physician or
- 24 prescriber in Cuyahoga or Summit County to whom
- 25 Actavis communicated any of the statements in any

- 1 version of the Kadian learning system?
- 2 A. I did not -- I did not undertake that
- 3 specific analysis, but I know from the testimony and
- 4 the documents in this case that the marketing plans
- and the marketing documents that I saw were
- 6 distributed nationally and used even locally in
- 7 Ohio.
- 8 Q. Do you know that these documents that we've
- 9 been looking at today were distributed in Cuyahoga
- 10 and Summit Counties?
- 11 A. Specifically this document, I don't have
- any -- anything that points to its actual use there
- other than, as I said, the testimony that the
- 14 marketing plans and the marketing materials were
- developed nationally and implemented in Ohio.
- 16 Q. I think you're referring to what you've
- 17 referred to all day as some of the aggregate data
- that you were referring to, right?
- MR. CHALOS: Object to the form.
- 20 A. There is actually a citation in my report I
- 21 think from -- quoting testimony from defendants that
- 22 specifically relates to this issue. So I can look
- for that and point you to that if you need me to.
- Q. I think my question is much more simple. I
- just want to know if you can identify any physician

- or prescriber in Cuyahoga or Summit who Actavis or
- 2 Allergan communicated with with respect to anything
- 3 related to Kadian marketing?
- 4 A. I quess I'm confused because it sounds like
- 5 to me that your question is asking me that if I say
- 6 no, I can't, then the conclusion that you would draw
- 7 from that is that none of the materials that we're
- 8 looking at today were used in Ohio and specifically
- 9 to these counties, and that's not accurate.
- 10 Q. My question is a yes-or-no question. Can
- 11 you identify a single physician or prescriber in
- 12 either Cuyahoga or Summit County to whom Actavis or
- 13 Allergan communicated any of the marketing
- information we've looked at today?
- MR. CHALOS: Object to the form.
- Q. And if you don't have any names, then --
- MR. CHALOS: Well, object to the form.
- 18 A. I actually have a long list of physicians
- 19 names in Cuyahoga and the other county that you
- 20 mentioned, they are from call notes from another one
- of the defendants, so I don't know that they would
- reflect any activities by your company, but they
- would reflect the names of physicians who were the
- recipients of the marketing that occurred in Ohio.
- Q. But you can't link it back to Allergan or

- 1 Actavis, correct?
- 2 A. Well, this kind of goes along with what I
- was saying yesterday, that -- when I was asked
- 4 another question along these same lines, that, you
- 5 know, the fact that I can't link a specific
- advertisement to a specific doctor doesn't mean that
- 7 the advertisements weren't present in the
- 8 marketplace, it doesn't mean the doctors didn't see
- 9 them, it just means that I haven't the tools at my
- 10 disposal to make that connection.
- 11 Q. And you haven't made that connection,
- 12 correct?
- 13 A. I make the connection by virtue of the fact
- 14 that I know these materials were used in Ohio and I
- know that doctors in Ohio saw them.
- Q. My question is a different one.
- 17 Can you identify any of the doctors who saw
- 18 them?
- MR. CHALOS: Object to the form.
- 20 A. Yeah, I mean, I can give you the -- I can
- give you doctors' names but it would be a
- 22 presumption that they did or didn't see it in any
- 23 individual case.
- Q. Okay. You talk about KOLs in your report.
- 25 A. Yes.

- 1 Q. And KOLs are key opinion leaders, right?
- The acronym KOL stands for key opinion leader?
- 3 A. That's right.
- 4 Q. In your report you talk about how KOLs are
- 5 influencers, right?
- 6 A. Yes. I -- that's not my terminology
- 7 necessarily. That's either industry or in some of
- 8 the defendants' terminology.
- 9 Q. Understood. So in Paragraph 67 of your
- 10 report, you include a quote: "Peer-to-peer
- 11 marketing uses key opinion leaders, or influencers,
- and word of mouth to create an expanding awareness
- and more rapid adoption of new pharmaceuticals by
- 14 prescribers and other stakeholders."
- Did I read that right?
- 16 A. Yes.
- 17 Q. Would you agree that in the context of this
- case, a KOL is an influential doctor in the field of
- 19 pain management?
- MR. CHALOS: Object to the form.
- A. KOL could be a pain management, it could be
- 22 addiction, it could be just -- in this case, it
- 23 could have been a general practitioner. It could
- have been a nurse, it could have been a lot of
- 25 different people.

Does simply being a doctor make someone a 1 Ο. 2. KOL? 3 Α. No. The --4 MR. CHALOS: Hold on. Object to the form; 5 incomplete hypothetical. So the requirements for KOL are completely 6 Α. 7 subjective and they are really up to the company 8 hiring the KOL or employing that strategy. The KOL would be -- and I saw a lot of documents in the 9 10 record that were evaluations of people who were 11 being considered as key opinion leaders, of 12 databases of people who were either past, present or 13 being considered for the future key opinion leaders, 14 and those people would be evaluated. Some of them 15 were eliminated because they weren't meeting up to 16 certain criteria. 17 So the whole idea of key opinion leadership 18 is one that is subjective to the company and if the 19 company thinks that it's a person that's an 20 influential prescriber or other type of practitioner, then that's up to them to decide. 21 The 22 point about what they are is that they are people 23 who influence the opinions of others, and in my report I refer to it -- and it was not my word, it 24 was the word of one of the defendant's witnesses --25

- that said key opinion leaders are used to infect
- other doctors with the ideas that they have.
- Q. Do you have any opinion as you sit here
- 4 today as to whether Actavis worked with key opinion
- 5 leaders?
- 6 A. I think the answer to that is that I do
- 7 have -- I have seen evidence that Actavis did --
- 8 well, Actavis I don't know specifically. Allergan
- 9 or Actavis, because in my analysis I made a note to
- try and determine if each company did indeed work
- with key opinion leaders or have key opinion leaders
- in their sort of cadre of people that they went to,
- and I know that I have a schedule in my report that
- we can look at that's broken down by manufacturer.
- 15 So we can go to that if you need me to look for a
- 16 document that shows that.
- 17 Q. Sure. I mean, do you know if Allergan or
- 18 Actavis worked with key opinion leaders? Is that
- 19 part of your opinion in this case?
- 20 A. I will let you know.
- So it appears that for Allergan I have four
- 22 entries: Dr. Chester Chorazy, David Sua, a person
- 23 called Nutel and Stewart Lewis.
- Q. Are you looking at -- Dr. Perri, are you
- looking at Schedule 18 in your report?

- 1 A. Yes, "Amounts Paid to Key Opinion Leaders."
- Q. Okay.
- A. Let me finish my review here.
- 4 Q. Sure. You just let me know when you are
- 5 done with your review.
- 6 A. Yes, ma'am. I'm sorry. It's taking just a
- 7 moment but these materials were originally in a
- 8 spreadsheet that was a lot easier to click on tabs
- 9 than it is to look through them.
- 10 Q. It's easier to search too, I'm sure.
- 11 A. Yep. Okay. So other than those four I
- mentioned, I don't see anything else that I can
- point to at this time.
- Q. Okay. And you've just identified four
- 15 names, right?
- 16 A. Yes.
- 17 Q. So let's take a step back. I know earlier
- 18 today you mentioned that you read -- I think you
- 19 said portions of Doug Boothe's testimony in this
- 20 case. Is that accurate?
- 21 A. Yes.
- 22 MS. ZOLNER: Do we have his testimony
- 23 available?
- MR. CIULLO: Uh-huh.
- 25 MS. ZOLNER: Can we mark that? Is that

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Exhibit 31? It's Page 363.
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- 2 (Perri Exhibit 31 was marked for
- 3 identification.)
- 4 BY MS. ZOLNER:
- 5 Q. Dr. Perri, we are going to flip specifically
- 6 to Page 363. Are you aware that Doug Boothe was the
- 7 CEO of Allergan?
- A. As I recall, his title was -- I can't recall
- 9 his exact title.
- 10 Q. Okay. Well, I'll represent to you that he
- was the CEO. And if you could look at Page 363,
- 12 starting at line 23, I'll read to you the question
- and I'll eliminate the objections and then read the
- 14 answer. Line 23 of page 363 of Doug Boothe's
- deposition.
- 16 Question: Were you aware of any KOL
- development at either Alpharma or Actavis when
- you were there?
- Answer: As I previously said, we at Actavis
- did no KOL activity for Kadian or any of our
- 21 generic approved products.
- 22 Question: Were you aware of any KOL
- development for any opioid products at Alpharma
- or Actavis?
- Let's just focus on the first part. Do you

- see where he said: Actavis did no KOL activity for
- 2 Kadian or any of our generic approved products?
- 3 A. Yes.
- 4 Q. Do you have any basis to dispute that
- 5 testimony?
- 6 A. No.
- 7 Q. Now, you referred to Schedule 18 of your
- 8 report.
- 9 A. Uh-huh.
- 10 Q. Which is the section about amounts paid to
- 11 KOLs and you first mentioned Chester Chorazy, right?
- 12 A. Yes.
- Q. Who is Chester Chorazy?
- 14 A. I don't know.
- 15 Q. How long has he been a KOL?
- 16 A. I don't know.
- Q. Who is he employed by?
- 18 A. I don't know.
- 19 Q. On what basis do you claim he was a KOL for
- 20 Allergan?
- 21 A. On the basis that he is on this list, but we
- 22 can pull that document and answer those questions.
- Q. Do you know anything about Mr. Chorazy's
- background as a KOL?
- A. No, I don't.

- Q. Do you know anything about his area of
- 2 expertise?
- A. As I said, his presence on this list tells
- 4 me there were amounts paid to him. That's what I
- 5 know.
- Q. Okay. What about David Sua, Nutal, or
- 7 Stewart Lewis, would the answer be the same for all
- 8 of those individuals?
- 9 A. Same answer for all of those, yes.
- 10 Q. In other words, you don't know who they are
- and you don't know how long they worked as a KOL?
- 12 A. I don't recognize those specific names, yes.
- Q. Do you have any opinion as to whether
- 14 Actavis worked with pain advocacy organizations to
- 15 promote opioids?
- 16 A. I don't think they did.
- 17 Q. Do you have any opinion as to whether
- 18 Allergan worked with pain advocacy organizations to
- 19 promote opioids?
- 20 A. Same answer.
- Q. I know this morning a drug called MoxDuo
- came up, and I don't want to put words in your mouth
- 23 but according to my notes, I think you mentioned
- 24 MoxDuo as an example of a drug that never made it to
- 25 market, correct?

- 1 A. Yes. It was not approved, right.
- Q. Okay. So it was not approved by the FDA; is
- 3 that accurate?
- 4 A. Not approved by the FDA and not marketed by
- 5 the company, either one.
- 6 Q. Okay. So that means no patient was ever
- 7 prescribed MoxDuo?
- 8 MR. CHALOS: Object to the form.
- 9 A. I guess that's true, yes, unless somebody
- 10 did something untoward.
- 11 Q. And your voice dropped. I think you said
- that MoxDuo was never marketed; is that accurate?
- MR. CHALOS: Object to the form.
- 14 A. That is my understanding, that MoxDuo didn't
- 15 ever launch.
- Q. Do you have any opinion as to whether
- 17 Actavis was involved in continuing medical education
- 18 courses?
- 19 A. I don't recall.
- Q. What about Allergan, do you have any opinion
- as to whether Allergan was involved in any
- 22 continuing medical education courses?
- A. Again, I don't recall specifically Allergan.
- Q. Is there anything that you could use to
- refresh your recollection on those?

- 1 A. Well, if I looked -- if I pulled the Kadian
- 2 marketing plans or other marketing plans, perhaps,
- 3 that would -- if they were going to do it, it would
- 4 be, generally speaking, in the marketing plans, so
- 5 we could look at that.
- Q. Yes. Okay. So that's going to be Exhibit
- 7 Number 32.
- 8 (Perri Exhibit 32 was marked for
- 9 identification.)
- 10 BY MS ZOLNER:
- 11 Q. I'm going to show you another document,
- Dr. Perri. This is ALLERGAN MDL 01104711, for the
- 13 record. The document is titled "Healthcare
- 14 Compliance Business Rules."
- 15 A. Okay.
- 16 Q. Have you seen this document before?
- 17 A. It does not look familiar to me, but I've
- 18 looked at a lot of documents.
- 19 Q. You have looked at a lot of documents.
- 20 A. I'm just beginning. Let me scan through it
- 21 and --
- 22 Q. Sure.
- MR. CHALOS: Is this number 32?
- MS. ZOLNER: It is.
- 25 A. There are certainly things in here that look

- familiar to me, but again, I can't say I've seen
- 2 this specific document.
- Q. The title of this document is "Sales"
- 4 Representative's Interactions with Healthcare
- 5 Professionals & Patients," correct?
- 6 A. Yes.
- 7 Q. And the effective date of this document is
- 8 January 5th, 2010?
- 9 MR. CHALOS: Hold on. Object to the form.
- 10 He just said he's never seen this document. If
- 11 you are just asking him to read it and say that's
- what it says, that's one thing, but I don't think
- you can ask him to affirm that that's true.
- 14 Q. Does the document represent that it was
- effective as of January 5th, 2010?
- 16 A. Yes.
- 17 Q. If you could look at Page 7, under
- 18 Educational Grants -- this is Section 12.0.
- 19 A. Yes.
- Q. Do you see under Section 12.2 in bold it
- 21 says: "At this time Actavis will not be offering
- 22 any educational grants?"
- A. It does say that in this document, yes.
- Q. Do you have any basis to dispute that
- 25 Actavis was not offering educational grants at this

1 time? 2. MR. CHALOS: Object to the form. 3 Α. So, I -- yeah. I -- I mean, I'm not 4 disputing that they are not involved. I don't have 5 a specific recollection of them being involved in 6 these programs, but I'm just uncomfortable drawing 7 conclusions from, you know, this cursory look at 8 this document that I haven't really had a chance to review or a document that I am not exactly sure 10 where it fits into the big picture of things that 11 I've examined in this case. I know that this --12 what this appears to be is a document where 13 Allergan/Actavis was sort of setting out the rules 14 of the road for a sales force that they were going 15 to employ. 16 Right. Ο. 17 So it -- it looks like it's consistent with Α. 18 what I would expect to see and it definitely says at 19 this time Actavis will not be offering any 20 educational grants. What I would point out is that 21 offering of educational grants is typically 22 something you find in the marketing plans for 23 branded products. So the fact that they are saying they're not going to do it at this time doesn't tell 24

me that they never did it. It just says they

25

- weren't planning on doing it right now.
- Q. Right. But a couple of questions ago I
- 3 think that you testified that you don't have any
- 4 recollection of whether Allergan or Actavis was
- 5 involved in any continuing medical education,
- 6 correct?
- 7 MR. CHALOS: Object to the form.
- 8 A. I think what I said was I didn't have a
- 9 specific -- a specific program that I could point to
- 10 that -- yes, so the answer is yes.
- 11 Q. What about general?
- MR. CHALOS: Object to the form.
- 13 Q. Do you have any general knowledge of any
- 14 continued medical education that Allergan or Actavis
- 15 was involved with?
- MR. CHALOS: Object to the form.
- 17 A. As I sit here right now, I can't -- I can't
- 18 have a -- I don't have an answer for that because I
- 19 just don't remember.
- Q. Okay. Do you have any opinion as to whether
- 21 Actavis ever hosted speakers bureaus?
- 22 A. Again, I need to look at the Actavis
- 23 marketing or the marketing plans because --
- Q. Have you not looked at those plans?
- 25 A. No, I have. I've just -- I've looked at

- 1 hundreds and hundreds of marketing plans and I can't
- tell you off the top of my head what's in every
- 3 single one of them. So if you are going to ask me a
- 4 specific question about that, I need to look at the
- 5 marketing plans to see if they laid out plans and
- then I would know which documents or what to look at
- 7 to know if those were actually enacted.
- Q. Do you have any opinion as to whether
- 9 Allergan ever hosted speakers bureaus?
- 10 A. Same answer.
- 11 Q. Okay. You just -- you don't know as you sit
- 12 here right now?
- 13 A. I would need to look the marketing plans to
- refresh my memory about what they did or didn't do
- specifically in each category for all of the
- 16 categories of marketing that I put in my report.
- 17 Q. You understand that Allergan is one of seven
- manufacturing defendants that has been sued in this
- 19 MDL, correct?
- MR. CHALOS: Object to the form.
- 21 A. The list is longer than seven but I
- understand that that's what we're talking about here
- today.
- Q. In preparation for your deposition today did
- you do anything to try to determine which

- 1 manufacturers were involved in what specific
- 2 marketing activity for purposes of preparation for
- 3 your deposition today?
- 4 MR. CHALOS: Object to the form.
- 5 A. I did a lot of review and a lot of
- preparation for this deposition but, unfortunately,
- 7 I don't -- I don't have a perfect memory and can't
- 8 recall every single thing that I've seen.
- 9 Q. I understand that, but I think you testified
- 10 earlier that you spent over 700 hours on this case
- and you've been paid somewhere around \$210,000, and
- 12 I am sure you spent a lot of time preparing for your
- deposition today, and one of the key areas of
- 14 expertise you are providing expert opinion on is
- peer-to-peer marketing, and I'm asking you questions
- 16 about that.
- And so what I'm trying to figure out is if
- 18 you have any understanding of whether Actavis or
- 19 Allergan ever hosted speakers bureaus?
- MR. CHALOS: Object to the form;
- 21 argumentative. It's a long admonishment
- preceding a question that he's already answered.
- MS. ZOLNER: To be clear, I am not trying to
- admonish the witness at all. I'm just trying to
- 25 make sure I understand his answer.

- 1 MR. CHALOS: Okay. Then don't admonish him.
- MS. ZOLNER: Agree to disagree on whether it
- was an admonishment. I think we're having a very
- 4 pleasant exchange.
- 5 MR. CHALOS: Object to the form.
- A. So a couple of things: Number one, I didn't
- 7 testify that I have been paid \$210,000. I gave that
- 8 as an estimate and I said if I get paid everything
- 9 that I billed.
- 10 Q. Understood.
- 11 A. That's number one.
- 12 O. I know how that works.
- 13 A. Number two, in my preparation I've looked --
- 14 I can tell you all kinds of things about Jennifer
- 15 Altier and the marketing plans for Kadian, I just
- 16 can't remember as I sit here right now whether
- 17 continuing medical education or advisory boards were
- part of all that. I do recall this, and I will give
- 19 you this information, that from her testimony, she
- 20 said that the marketing was basically like a
- 21 glorified package insert, so my thinking is maybe
- 22 I'm not remembering because it didn't happen, but
- until I see the documents, I can't tell you for sure
- one way or the other.
- MR. CHALOS: Why don't we take a break?

- 1 We've been going a little over an hour.
- Q. Do you want to take a break?
- 3 A. Yes.
- 4 Q. Okay.
- 5 A. Yeah.
- 6 MS. ZOLNER: Let's go off the record.
- 7 THE VIDEOGRAPHER: We are now going off the
- video record. The time is currently 3:36 p.m.
- This is the end of Media Number 5.
- 10 (Recess from 3:36 p.m. until 3:49 p.m.)
- 11 (Mr. Chalos is no longer present.)
- 12 THE VIDEOGRAPHER: We are now back on the
- video record with the beginning of Media
- Number 6. The time is currently 3:49 p.m.
- 15 BY MS. ZOLNER:
- 16 Q. Dr. Perri, do you have any opinion as to
- 17 whether Actavis ever worked with medical science
- 18 liaisons?
- 19 A. I don't recall specifically in the materials
- that I reviewed reading about MSLs at Actavis, but
- 21 the -- I might not have seen that in the marketing
- documents because MSLs are separate from marketing.
- I might have seen it as a result of overlap, but I
- don't recall specific to your -- to your defendant.
- Q. What about anything general that relates to

- 1 Actavis?
- 2 A. I only saw a couple of documents that
- 3 related to MSLs. There is one place in my report
- 4 that I recited -- I cited MSLs with respect to
- 5 gathering of information at a -- like an American
- 6 Pain Society meeting, and I'm trying to remember
- 7 what the section of the report was, but I -- as I
- 8 sit here, I would have to look to see which
- 9 defendant that was.
- 10 Q. But you don't recall specifically that it
- 11 would have been Actavis; is that right?
- 12 A. I don't think it was Actavis, but again, I
- wish I could type in MSL and go right to that
- section in my report and give you an exact answer to
- that question, because it is possible, I just need
- 16 to look, so --
- 17 Q. What about Allergan, do you have any opinion
- as to whether Allergan ever worked with medical
- 19 science liaisons?
- 20 A. Same answer for Allergan.
- Q. Do you have any general opinions as to
- 22 whether Allergan --
- A. Did you or didn't you want me to get an
- 24 answer to that for you? Because I was looking --
- Q. Oh, I'm sorry. I didn't realize you were

- 1 looking.
- 2 A. Yeah.
- Q. Dr. Perri, are you looking for where you
- 4 talk about MSLs in your report?
- 5 A. Yes.
- Q. Do you want me to give you some help?
- 7 A. It's up to you.
- Q. You might be looking at Paragraph 60.
- 9 A. I'm at 69 going in that direction, so I was
- in the right place.
- 11 Q. Okay. It's been a long day, so -- ease of
- 12 reference.
- 13 A. Yeah. So it was Allergan that is the
- 14 example that I cited in my report.
- Q. Are you referring to the line of your
- 16 report: Allergan -- for example, Allergan MSLs
- 17 collected marketing intelligence at an American Pain
- 18 Society meeting focused on the potential dangers of
- 19 opioid use; is that right?
- 20 A. Yes.
- Q. What Allergan MSLs are you speaking of here?
- 22 A. Whichever ones the deponent was speaking
- about in that deposition testimony. I don't think I
- have names.
- Q. You don't have any names. Do you know what

- 1 MSLs were collecting the market intelligence at an
- 2 American Pain Society meeting?
- 3 A. So I remember this document pretty well but
- I don't remember the specifics of who, but I know
- 5 there were -- there were sections for -- of input
- from MSLs providing what I refer to as market
- 7 intelligence on the landscape of the pain -- on the
- 8 opioid market.
- 9 Q. Do you know how many MSLs were at that
- 10 meeting?
- 11 A. Without -- and I think -- I think I cite
- that document in Number 88, so I'm sure if it's
- important for you to know how many were there, we
- 14 can pull that document and look at it.
- 15 Q. In your report it says: For example,
- 16 Allergan MSLs collected marketing intelligence at an
- 17 American Pain Society meeting focused on the
- 18 potential dangers of opioid use.
- 19 It's singular in this report. Is that
- 20 accurate?
- 21 A. That it was one meeting? An example, this
- is a singular example, yes.
- Q. Okay. Let's look at Exhibit 33.
- 24 MS. ZOLNER: Thank you. This is a document
- that's Bates numbered Allergan MDL 00194340.

(Perri Exhibit 33 was marked for 1 2. identification.) 3 THE WITNESS: Good idea. Thank you. 4 MS. BAISCH: Do you have another one of 5 those? MR. CIULLO: I do. 6 BY MS. ZOLNER: 7 8 Ο. This document is dated June 27, 2012. 9 A. Yes. 10 And if you go down to the first e-mail, the 11 initial e-mail in this chain, it's from Terrence 12 Fullem. Do you see where I am? 13 Α. Yes. 14 Q. It says: "All, as you know, we have had to 15 let the MSLs and NAMs go due to the CRL on Moxduo." 16 First of all, what is a NAM? 17 National account manager. Α. 18 Okay. Do you have any understanding of what Q. 19 this sentence means? 20 MS. BAISCH: Object to form. 21 So my purpose of citing this MSL example 22 here was to simply show the utility of these kind of 23 personnel within the marketing organization and to 24 demonstrate the role that they could play. Whether

they were fired later on or let go because of the

25

- 1 status of the product they might have been working
- on, Moxduo not being launched, is really not
- 3 relevant to my analysis. What is relevant is this
- 4 is how MSLs can interact within the marketing
- organization within a company, that's all.
- Q. Understood. And I'm just trying to
- 7 understand exactly to what extent Actavis or
- 8 Allergan used MSLs, and that's why I'm asking these
- 9 questions, just to get a sense of magnitude or lack
- of magnitude.
- 11 A. Okay.
- 12 Q. The NAM that's referenced here, you've
- defined that. What about the CRL, what does that
- 14 acronym stand for?
- 15 A. That, I don't know. I've seen a lot of
- 16 acronyms that --
- 17 Q. I think it might be a misprint and I think
- it might be CLR -- or CRL, complete response letter?
- 19 A. It could be that. When I first saw it I
- thought clinical research liaisons, but that doesn't
- 21 make any sense in the context of the sentence, so --
- 22 Q. But this seems to indicate that in this
- particular instance that you've cited in your
- 24 report, that the MSLs were released after the FDA
- rejected the Moxduo product, right?

- 1 MS. BAISCH: Object to form.
- 2 A. I don't think I cited that in my report. I
- 3 think that's evidenced here in this e-mail.
- 4 Q. Would you agree that this suggests that
- 5 Actavis was working with MSLs for purposes of going
- 6 to market with Moxduo?
- 7 MS. BAISCH: Object to form.
- 8 A. So given my recollection, even though we
- don't have the document here in front of us, of the
- document that's cited in Reference 88, the e-mail
- and slide presentation, that lists a lot of the
- 12 factual things that the MSLs actually provided in
- terms of market intelligence, and given this
- document, it seems like that the MSLs were used
- 15 prior to the launch of Moxduo, and at least this
- document says that the MSLs were let go because of
- 17 the fact that Moxduo didn't launch.
- 18 Q. Are you speculating right now?
- 19 A. I mean, I thought I was agreeing with you,
- 20 actually, but do you have a specific question?
- 21 Because maybe I --
- Q. Let me try to unpack this in a different
- 23 way. We talked earlier about the fact that Moxduo
- was a drug that never went to market, correct?
- 25 A. Correct.

- O. And this document that we have marked
- 2 Exhibit Number 31 --
- 3 A. 33.
- 4 Q. -- 33, thank you, Dr. Perri, suggests that
- 5 MSLs were being used for purposes of Moxduo and a
- 6 potential launch of that drug, right?
- 7 A. Actually, I don't really read it that way,
- 8 it's that because Moxduo wasn't launching, they had
- 9 to let them go. I mean, it could be financial, it
- 10 could be that they just couldn't afford it anymore.
- 11 Q. Fair enough.
- 12 A. So I don't try to draw conclusions about
- 13 that.
- Q. Fair enough. Well, let me ask you a simpler
- 15 question. Do you have any basis to believe that
- 16 Actavis worked with MSLs in connection with any
- other drug besides Moxduo?
- 18 A. Well, I can tell you for sure that any
- information they gained on the opioid marketplace as
- 20 a result of their attending of the American Pain
- 21 Society meeting that I cite in Reference 88 would
- have benefited the companies marketing organization
- for any product they were bringing to market.
- Q. That wasn't my question. Do you have any
- 25 basis to believe that Actavis worked with MSLs in

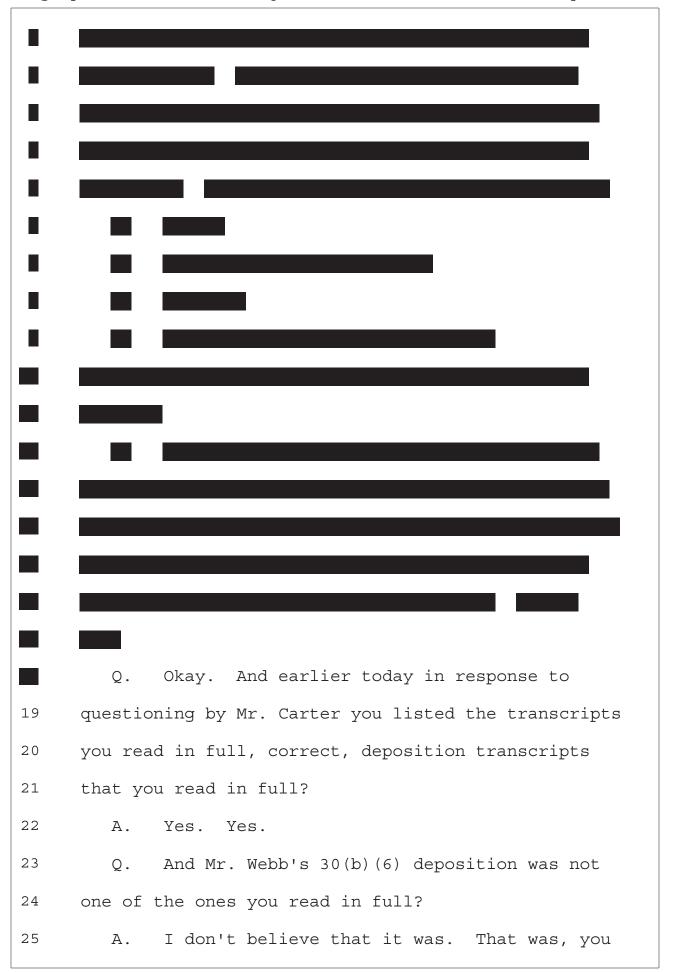
- 1 connection with any other drug besides Moxduo?
- A. Again, you're making the connection that
- 3 this was completely related to Moxduo and I don't
- 4 draw that conclusion in my report.
- 5 Q. Can you give me other examples of Allergan
- 6 working -- Allergan or Actavis working with MSLs,
- other than the document that we're looking at here
- 8 and the document you cite?
- 9 A. Okay. So let me finish what I was saying.
- 10 Q. Sure. I didn't mean to interrupt you.
- 11 A. So the connection that you're making is
- 12 that -- and it may be true, I don't know the answer
- to this question, but you're drawing the conclusion
- 14 that the MSLs in this example were working for
- 15 Moxduo. It's possible that's true. It's possible
- 16 that it's not true. I don't -- I don't know the
- answer to that question based on what I have here in
- 18 front of me.
- What I do know is from a marketing
- perspective, and this is my analysis in the case,
- what I was concerned about, what I was focused on
- 22 was did Allergan -- did any of the defendants
- utilize MSLs in any way related to their marketing
- organization, because in my experience, MSLs are a
- valuable resource when it comes to providing

- information to the marketing department. And while
- they aren't in the sales force, they're a very
- 3 valued part of the company and play a vital role.
- 4 So I was simply using this as an example to show how
- 5 the MSLs could collect information.
- These other issues about Moxduo and whether
- 7 they were working for Moxduo or for something else
- 8 weren't on my radar screen.
- 9 Q. Got it. Okay. Will you opine in this case
- that any particular opioid medication is more
- dangerous than another?
- 12 A. I don't carry a specific opinion about the
- drugs in this case per se, so no.
- Q. What about general?
- 15 A. Just that opioids are dangerous drugs,
- 16 that's all.
- Q. But again, you're not going to be opining on
- any particular opioid medication being more
- 19 dangerous than another?
- A. No, I don't think so, no.
- Q. Will you opine that marketing for one type
- of opioid product is more problematic than others?
- A. No, and I'll just -- I will reiterate that
- 24 my analysis was based on the collective marketing
- and the marketing is intertwined and you can't

- single out one drug's marketing from the rest
- without losing the richness of the context of the
- 3 marketing of opioids.
- 4 Q. You're looking at marketing in an aggregate
- form, you're not looking at the sum of the parts?
- A. I looked at the parts to form the aggregate
- 7 opinion.
- Q. Is it your testimony that you looked at all
- 9 of the parts?
- 10 A. I looked at as many parts as I could locate
- and had time to analyze, yes.
- 12 Q. But again, you're not offering any opinions
- about any of the specifics about any of the
- defendants in this case, meaning that when we first
- started talking earlier today I asked if you were
- 16 offering any specific opinions about Allergan and
- 17 Actavis and you said no.
- 18 A. That's right.
- 19 Q. And I think that would be the case for all
- of the defendants that are involved in this
- 21 litigation, correct?
- 22 A. It is, but I'm sure that everyone will still
- ask me that question.
- Q. You're right.
- A. But just to be 100 percent clear, I don't

```
have any opinions about any drugs or any particular
 1
 2.
      single actions. My opinions are the summation of
 3
      what I've reviewed all taken together. So while the
     marketing behaviors were examined individually, in
 4
 5
     other words, I did look at the Kadian marketing plan
     by itself, regardless of whether Kadian was a
 6
 7
     product of your company or some other company, I
 8
      looked at the Kadian marketing plan, and then beyond
      that, I looked at the companies to the best degree
10
      that I could, and then took all of those companies
11
      together to form my aggregate opinion.
12
              MS. ZOLNER:
                           Thank you, Dr. Perri.
13
         appreciate your time.
14
              THE WITNESS: Thank you.
15
                           I don't have any further
              MS. ZOLNER:
16
         questions at this point.
17
              THE WITNESS:
                            Thanks.
18
              THE VIDEOGRAPHER: We are now going off the
         video record. The time is currently 4:02 p.m.
19
20
            (Recess from 4:02 p.m. until 4:05 p.m.)
21
              THE VIDEOGRAPHER: We are now back on the
22
         video record. The time is currently 4:05 p.m.
23
                        CROSS-EXAMINATION
24
     BY MS. BIERUT:
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- 1 know, based upon a memory of what I was looking
- through, that list of depositions. I know that
- 3 there were several sections of his that I recall,
- 4 but I can't say for sure, so I didn't include him on
- 5 the list.
- 6 Q. Okay. And how about Mr. Webb's fact
- 7 deposition, did you read that as well?
- 8 A. See, and that's the part that makes me
- 9 wonder if I read his 30(b)(6), because it is ringing
- 10 a bell, but again, I can't promise -- he asked me if
- I read each and every word of those depositions, and
- as I recall with Mr. Webb, I read part of his
- depositions and other parts I skipped over.
- Q. How did you identify which parts to read?
- 15 A. Well, for example, the parts on people's
- 16 background and education, if they had been deposed
- 17 before, I would skip through a lot of that.
- 18 Q. Okay. Let's turn to your report at
- 19 Page 135, and at "Theme Three: Opioid should be
- 20 first-line therapy for pain."
- 21 A. Yes.
- Q. Did I read that correctly?
- 23 A. Uh-huh.
- Q. Okay. And then on Page 136, Note 311, one
- of the documents you cite here is "Exalgo Account

- 1 Executive Customer Presentation, " correct?
- 2 A. Yes.
- Q. And it's Bates number MNK-T1 0002321267?
- 4 A. Yes.
- 5 Q. Did you read this entire document before you
- 6 cited it?
- 7 A. I'm sure I did. I'd need to look at the
- 8 document to see what is contained in it so I know
- 9 for sure.
- 10 Q. Yeah. And are you aware that Exalgo is
- indicated for a risk-tolerant -- I'm sorry, for
- 12 opioid-tolerant patients only?
- 13 A. Yes.
- 14 Q. Okay.
- 15 A. Yeah.
- Q. Let's go to Page 82.
- 17 A. Give me just one second, please.
- 18 So just in terms of that, this document is
- 19 cited with respect to breakthrough paper, so I'm
- 20 pretty sure that's why it's in this reference. So
- I'm not sure exactly about your question, but we are
- 22 within a section but within that section there are
- 23 different topics being discussed.
- Q. Okay. But you do know that Exalgo is
- indicated for breakthrough pain -- I'm sorry, for

- opioid-tolerant patients only?
- 2 A. Yes. I mean, it's once daily dose sort of
- dictates that that would be the case, yes.
- 4 Q. Okay.
- 5 A. Good.
- 6 Q. Moving toward Page 82 of your report, you
- 7 state that: "One of the barriers to opioid
- 8 prescribing has been the potential for and fear of
- 9 addiction. Numerous marketing messages used by
- 10 Defendants communicated information that supported a
- change in the paradigm regarding the link between
- 12 addiction and opioids."
- Do you see that?
- 14 A. I do.
- 15 Q. Okay. And one of your examples is on the
- 16 next page, Page 83: "Mallinckrodt's communication
- of the message that MNK-795 (oxycodone/APAP extended
- release), 'provides fast-acting and long-lasting
- 19 relief without concerns about abuse.'"
- Do you see that?
- 21 A. I do.
- Q. And then in Footnote 266 --
- 23 A. Yes.
- Q. -- you state that: "This is a compound that
- 25 would come to market as Xartemis."

- 1 Correct?
- 2 A. Yes.
- Q. So are you aware that Xartemis launched in
- 4 March 2014?
- 5 A. About then, yes.
- 6 Q. Okay. And then -- we're making good time.
- 7 Direct you to look at your report on
- 8 Page 14.
- 9 A. Page 14?
- 10 Q. Uh-huh. The last bullet on that page -- I'm
- 11 sorry.
- 12 A. Yes.
- 13 Q. Okay. The last bullet on that page is:
- 14 "Pharmaceutical marketers take advantage of the
- medical community's reliance on scientific evidence
- by not only providing science-based messages
- directly through their marketing, but also through
- 18 funding and sponsoring clinical research, clinical
- 19 practice guidelines, and continuing medical
- 20 education."
- Do you see that?
- 22 A. I do.
- Q. And on page 86 is your marketing messages
- 24 table?
- 25 A. Yes.

- 1 Q. The first entry there is a presentation at a
- 2 2015 American Academy of Pain Medicine Annual
- Meeting with a Mallinckrodt-sponsored study; is that
- 4 right?
- 5 A. Yes.
- 6 Q. And you cite in the Bates column a link to
- 7 the abstract?
- 8 A. Yes.
- 9 Q. So was it clear to you from this citation
- that the study was sponsored by Mallinckrodt?
- 11 A. Do you happen to have a copy of the abstract
- 12 there or --
- O. Not on me.
- 14 A. As I recall, and again, lots of documents
- 15 here, that it was linked to a support by
- 16 Mallinckrodt.
- 17 Q. Okay. And did you read the study itself?
- 18 A. I know I read the abstract at least, yes.
- 19 Q. So you have no opinions on the scope of the
- 20 study?
- 21 A. Just what I would glean from the abstract,
- which is basically included in this paragraph.
- Q. And no opinion on the methodology of the
- 24 study?
- A. No, I don't have an opinion on the

- 1 methodology as we sit here.
- Q. And no opinion on whether the conclusion was
- 3 sound from a clinical perspective?
- 4 A. No.
- 5 MS. BIERUT: That's it for me. Thank you.
- 6 THE VIDEOGRAPHER: We are now going off the
- 7 video record. The time is now currently
- 8 4:13 p.m.
- 9 (Recess from 4:13 p.m. until 4:16?p.m.)
- THE VIDEOGRAPHER: We are now back on the
- video record. The time is currently 4:16 p.m.
- 12 CROSS-EXAMINATION
- 13 BY MR. HENNESSY:
- Q. Good afternoon, Dr. Perri. My name is Sean
- 15 Hennessy and I'm with the law firm Arnold & Porter
- 16 and I'm here today on behalf of the Endo and Par
- 17 Pharmaceutical defendants. I understand that I'm
- the last person that stands between you and the
- door, so I will do my best to be appropriately
- 20 focused with my questions.
- 21 A. Thank you.
- Q. Am I correct that you are not offering any
- 23 Endo-specific opinions in your report?
- 24 A. Yes, you are.
- Q. Okay. And I'm also correct that you're not

- offering any Par-specific opinions in your report?
- 2 A. That would be correct.
- Q. And to put a finer point on that question,
- 4 specifically, you're not offering any opinion in
- 5 this case that any of Endo's marketing statements
- 6 were false or misleading?
- 7 A. I was relying on other experts to make that
- 8 judgment, if they made it.
- 9 Q. And you've stated in your report that the
- 10 assumption, relying on other experts, is consistent
- 11 with FDA documents, in particular warning letters,
- regarding the false and misleading nature of
- defendants' marketing; is that correct?
- 14 A. For some products, yes.
- 15 Q. Okay. To your knowledge did Endo receive
- any warning letters for any of its Opana promotional
- 17 materials?
- 18 A. I can't recall, and I know that there is a
- 19 citation that lists all the drugs here in the
- report, and there are about 11 or 12 that are named.
- I just, as I sit here, I can't recall if Opana is
- 22 one of them.
- Q. And if the citations in your report don't
- include any FDA warning or other letters regarding
- 25 Endo's Opana labeling, is it fair to say that you're

- 1 not aware of any?
- 2 A. I'm not aware of any in addition to this,
- 3 that's right.
- 4 Q. Okay. And we've talked a little bit or a
- 5 lot today about Table II in your report. I noticed
- 6 that Table II in your report doesn't include any
- 7 Endo marketing statements regarding Percocet. Does
- 8 that sound right?
- 9 A. That's probably correct, yes.
- 10 Q. Does any part of your opinion concern Endo's
- 11 marketing of Percocet?
- 12 A. That is a more difficult question to answer
- because the opinion apply -- my opinion applies to
- 14 all opioids being marketed, because it's my -- it's
- my contention that the marketing by any -- the
- 16 marketing of any opioid is impacting the marketing
- of all opioids by virtue of the impact that it has
- on the marketplace, the education of physicians and
- other prescribers, the other stakeholders, the
- supply chain, so it's all interrelated.
- Q. Is it fair to say that you haven't
- identified any specific messages relating to
- 23 Percocet that Endo used?
- 24 A. I'm sure that's true. There may be -- there
- 25 may be messages in the more complete listing of

- search -- the search results for marketing messages
- that I requested contains a lot of documents that I
- didn't cite in Table II, so there may be some in
- 4 there related to Percocet, but as I recall, I have
- 5 not seen specific marketing documents related to
- 6 Percocet other than perhaps a marketing plan, an old
- 7 marketing plan or something like that.
- Q. Am I correct that you have not attempted to
- measure the extent to which Endo's marketing
- influenced opioid prescribing decisions?
- 11 A. Yes. So my opinion is that opioid marketing
- influenced prescribing decisions, but I did not
- undertake any analysis to assign blame or
- 14 percentages to any one drug or any one manufacturer.
- 15 Q. Okay. Are you offering any opinion as to
- which doctors in Summit or Cuyahoga Counties
- 17 prescribed opioids because they were influenced by
- 18 Endo's marketing?
- 19 A. I think my opinion is, is that all doctors
- in Summit and Cuyahoga Counties were influenced by
- opioid marketing, but I cannot draw a link between a
- 22 particular ad and a particular doctor and say that
- this ad caused that doctor to do some other
- behavior. I've been asked that question a lot of
- times today and I guess I am struggling with some

- way to answer it better, because I don't seem to be
- 2 getting my point across very well with it, but at
- 3 the end of the day, from a marketing perspective,
- 4 opioid marketing impacted doctors' prescribing. We
- 5 see that in the results the companies obtained
- 6 themselves in their marketing metrics and other
- 7 documents.
- 8 So to say that there is no link between
- 9 them, I can't do that, but again, I haven't
- 10 quantitated it and I can't point to a specific
- 11 doctor.
- 12 Q. And you can't point to a specific
- manufacturer related to a doctor either; is that
- 14 correct?
- 15 A. That's right. My analysis was in the
- 16 aggregate, so I wouldn't point -- I wouldn't point
- to any one manufacturer.
- 18 Q. Okay. Yesterday, if my memory serves me
- 19 correctly, I believe you testified that you reviewed
- defendants' sales calls notes; is that correct?
- 21 A. Yes, but I think the sales calls notes were
- 22 primarily from just a couple manufacturers. I think
- it was primarily Purdue.
- Q. Do you remember if you reviewed Endo's sales
- 25 call notes?

- 1 A. I don't recall Endo's sales call notes.
- Q. And so fair that you didn't identify any
- 3 Endo sales call notes indicating that any doctor
- 4 changed his or her prescribing decision in any way
- 5 as a result of Endo's marketing?
- 6 MS. BAISCH: Object to form.
- 7 A. I think my answer to your previous question
- 8 would require me to answer that question the same
- way, is that I don't -- I didn't do that analysis to
- assign a doctor's behavior to a particular cause on
- 11 the marketing side.
- 12 Q. Can you say to a reasonable degree of
- scientific certainty that the opioid crisis would
- 14 look any different in Cuyahoga or Summit Counties if
- 15 Endo did not market and sell opioids?
- 16 A. You know, that's -- again, that's not
- 17 something that I examined, but if you -- if you look
- at my opinions and my Opinion 7 is that the opioid
- 19 marketing expanded the opioid market. If you were
- 20 to take -- in a hypothetical situation, if you were
- to take one manufacturer out, that would have left
- some kind of a void, would somebody else have filled
- that void? I just don't know the answer to that
- question, so I think the answer is I don't know.
- Q. Okay. Do you have Exhibit 1 in front of

- 1 you, your report?
- 2 A. I do, yes, sir.
- Q. My understanding is that you identified
- 4 three marketing themes that you allege were used by
- 5 the defendants in this case, and one of those
- 6 themes, which I believe is cited on Page 82 of your
- 7 report, is that -- I'm quoting it. I should quote
- 8 from the document.
- 9 Is that: "Dependence, tolerance, addiction
- and withdrawal should not be a concern in
- 11 prescribing opioids."
- 12 Is that correct?
- 13 A. That is one of the themes that I settled on,
- 14 yes.
- Q. Okay. And I believe you testified that you
- reviewed the FDA-approved prescribing information
- for the defendants in this lawsuit; is that correct?
- 18 A. Yes. I said that I made an effort to find
- 19 the package inserts for the various products
- involved in this litigation over time, and while I
- 21 can't -- I don't have a table that says I saw one
- from each year, I think I've seen the vast majority
- of the PIs that were available.
- Q. Do you recall whether you reviewed Endo's --
- any of Endo's FDA-approved PIs for Opana ER?

- 1 A. I'm sure I did, yeah.
- Q. Are you aware that Endo's FDA-approved Opana
- 3 ER PI warned about the risks of dependence,
- 4 tolerance and addiction?
- 5 A. Yes, I am.
- Q. And are you aware that among other places,
- 7 those risks were warned about in the black box
- 8 warning section of Endo's Opana ER PI?
- 9 A. Yes.
- 10 Q. You got a question earlier today about the
- meaning or the significance of a black box warning,
- and is it fair to say that a black box warning is a
- concise and prominent way to warn about the serious
- risks associated with a prescription opioid product?
- 15 A. Precise I would agree with you. Prominent
- 16 with respect to the PI itself, but in terms of the
- overall marketing, no, I wouldn't agree with that,
- 18 so --
- 19 Q. But as to the PI, would you agree with that
- statement, that the black box warning is a concise,
- 21 prominent warning containing the serious risks
- associated with an opioid product?
- 23 A. And if you add to that within the PI --
- O. Within the PI?
- 25 A. Yes.

- 1 Q. In your review did you identify any
- 2 FDA-approved PIs for Opana ER that did not warn
- about the risks of dependence, tolerance and
- 4 addiction?
- 5 A. No, I did not.
- Q. I believe you've acknowledged in your
- 7 report, and in your testimony as well, that
- 8 pharmaceutical manufacturing materials -- excuse me.
- 9 Strike that.
- I believe that you've acknowledged in your
- 11 report and in your testimony that pharmaceutical
- manufacturers' marketing materials must be
- consistent with the FDA-approved PI; is that
- 14 correct?
- 15 A. Yes, and beyond that I've said that the PI
- 16 provides the boundaries as far as, you know, the
- 17 latitude that you have to -- the information. So
- it's not surprising at all that many of the
- 19 marketing messages are things that are found in the
- 20 PIs, as we've seen in some of the other testimony
- and documents that I've been shown today.
- The thing that I feel like it's overlooked
- 23 in all of this is two things: Number one is that
- the PI is not a prominent piece of information that
- people, you know, are constantly relying on, are

- 1 constantly being exposed to, and the other is, is
- 2 that it -- the information in the PI is expected to
- be communicated in marketing. That's why so many
- 4 times it's shown up in Table II. The question is
- what does all that marketing do, and that's what
- 6 I've tried to analyze in my report.
- 7 Q. I believe that you also testified that
- 8 you've reviewed sales training materials as part of
- 9 your analysis; is that correct?
- 10 A. I have reviewed some sales training
- 11 materials, yes.
- 12 Q. Did you review Endo's sales training
- 13 materials?
- 14 A. I would have to look to see specifically
- what from Endo I might have seen. The sections in
- 16 my report that deal with objection handlers and
- those types of sales training materials would be
- where I would go to look.
- 19 Q. If it's helpful, there are a couple of sales
- training materials for Endo that you cite in
- 21 Table II.
- 22 A. Okay.
- Q. So that would suggest that you, as part of
- your analysis, you reviewed Endo sales training
- 25 materials?

- 1 A. At least -- at least those documents, yes,
- 2 and my expect -- if they are cited in Table II, my
- 3 expectation is they are probably cited elsewhere
- 4 too.
- 5 Q. Are you aware that Endo trained its sales
- 6 representatives on the promotional messages that
- 7 were approved for use with healthcare providers?
- 8 A. The -- I think I answered that just a moment
- 9 ago when I said that the PI sets out the boundaries
- and that the messages contained in the PI are the
- ones that I would expect to see in the sales
- training materials, so I think yes.
- Q. Okay. And as part of your analysis did you
- learn that Endo provided its sales reps with
- approved promotional materials that they were
- 16 permitted to use when they were detailing healthcare
- 17 providers?
- 18 A. Yes, Endo and others were -- had materials
- that they had both approved for use and materials
- that were not for general distribution, yes.
- Q. And often the materials that fall under the
- latter category, not for general distribution, were
- labeled as such with a footer or other sort of
- 24 marketing; is that correct?
- 25 A. Yes.

- 1 Q. Did you cite any materials that fall under
- that latter category, that were not for promotional
- 3 use in Table II, do you recall?
- 4 A. I don't recall off the top of my head. I
- feel like in my report, though, there are places
- 6 where materials that were not intended for
- 7 distribution were cited, yes.
- 8 Q. You testified yesterday, I believe --
- 9 A. Can I add something to that?
- 10 Q. Sure.
- 11 A. Specifically with respect to Endo, I know
- that there were materials that are cited with regard
- to Endo in particular that were never distributed.
- 14 Whether they were marked not to be distributed or
- not, I can't recall, because it was -- it was -- the
- 16 example that's coming to mind is one that, as I
- mentioned this morning, and you maybe are going to
- 18 ask me --
- 19 Q. I'm going to ask you about that.
- 20 A. Okay. Well, I'll just save it. That's
- 21 fine.
- 22 Q. I believe you testified yesterday that you,
- in your analysis, you relied on defendants'
- 24 marketing plans; is that correct?
- 25 A. Yes.

- 1 Q. And you would agree that marketing plans are
- 2 not used by pharmaceutical companies in their
- 3 communications with healthcare providers; is that
- 4 fair?
- A. Yes, that's fair. The marketing plans are
- 6 internal company documents that are very detailed,
- 7 very specific, very much the rules of the road when
- 8 it comes to what we're going to do and not going to
- 9 do, and they are intended to guide and direct the
- 10 marketing effort.
- 11 Q. And you haven't seen any instances where
- 12 Endo's sales representatives took a marketing plan
- out into the field and presented that to a doctor;
- is that correct?
- 15 A. I have not, and that wouldn't make any sense
- 16 for them to do that. It wouldn't be relevant to
- 17 their -- to their efforts with the doctors, but what
- the marketing plans do map out is the strategy, the
- themes, the core messages, the focus.
- Q. Marketing plans are not distributed to
- anyone outside the company for promotional purposes?
- 22 A. In my experience, I have not seen that
- happen, no.
- Q. Are you familiar with Endo's master visual
- 25 aids for Opana ER?

- 1 A. Master visual aids? That's not ringing a
- 2 bell.
- 3 Q. Okay. There is one that you --
- 4 A. Oh, yeah.
- 5 Q. There is one that you cite and I'm going to
- 6 show you that one in a moment. You cite it in
- 7 Table II. I'm just curious, do you recall whether
- 8 or not you reviewed all of the master visual aids
- 9 for Endo for Opana ER, or just that single --
- 10 A. The whole concept of the master visual aids,
- I recall that term now, and I know that there were
- 12 numerous visual aids that were referred to in that
- 13 context, yeah.
- Q. Do you understand that that master visual
- aid for -- as far as Endo goes, it's the primary
- 16 document that Endo's sales representatives were
- 17 required to use when they were detailing doctors?
- 18 A. As I recall, that was the purpose of that
- 19 document.
- 20 Q. In formulating your report, did you consider
- 21 Endo's guidance to its sales representatives
- 22 concerning the information that they were required
- to present to healthcare providers?
- A. Could you do that one more time.
- Q. Sorry.

- 1 A. I lost you on the front end of that.
- Q. Let me go a little slower on this one. In
- formulating your report, did you consider Endo's
- 4 guidance to sales representatives concerning the
- 5 information that they were required to present to
- 6 healthcare providers?
- 7 A. Yes.
- 8 Q. Okay. And so do you understand that Endo's
- 9 sales representatives were required to present the
- 10 complete indication for Opana ER?
- 11 A. Yes, I do know that.
- 12 Q. And do you understand that Endo's sales
- representatives were required to present the product
- risks when they were detailing doctors?
- 15 A. The Opana marketing plans definitely would
- 16 support that, yes.
- Q. And do you understand that Endo's sales
- 18 representatives were specifically instructed that
- they must present the black box warning and the
- important safety information for Opana ER?
- 21 A. Yes. Also, the marketing plans would
- 22 support that.
- Q. Okay. Are you aware that Endo monitored its
- sales representatives to ensure that they complied
- with these promotional policies?

- 1 A. I know Endo monitored its employees, yes, to
- 2 the extent for monitoring that specific -- those
- 3 specific behaviors, and others, such as their sales
- 4 performance and so forth.
- 5 Q. You identified in your report, I think it's
- maybe in a couple places, the PhRMA, P-h-R-M-A, Code
- 7 of Interactions with Healthcare Providers as an
- 8 example of a standard that pharmaceutical companies
- 9 should adhere to in their marketing. Is that right?
- 10 A. That's correct.
- 11 Q. Are you aware that Endo voluntarily adopted
- 12 the PhRMA code?
- 13 A. I don't know that I was aware of that or
- 14 not. I know that -- my understanding is, is that
- 15 all companies have adhered -- voluntarily adhered to
- 16 that.
- 17 Q. Are you aware that Endo incorporated the
- 18 PhRMA code into its own compliance policies
- 19 requiring that all of its employees follow those
- 20 requirements?
- 21 A. I don't have an opinion one way or the other
- 22 about that. I -- it sounds like it would be
- 23 correct, if they are voluntarily adhering to the
- code.
- Q. Is that something that you considered in

- 1 formulating your opinion?
- 2 A. So, you know, in the opinion it -- there are
- different levels of adherence to the code. I mean,
- 4 at one level we have: "Hey, that's a great idea."
- 5 At another level: "What are we doing in
- 6 your planning?"
- 7 In another level: "What are we doing
- 8 operationally?"
- 9 But the analysis that I undertook was
- 10 slightly different than that. It was to examine the
- 11 marketing of the opioids without respect to Endo or
- 12 Allergan or anybody else, but to look at the
- marketing that was implemented for the opioids, and
- then to assess at the end of the day did that
- marketing, not Endo or somebody else, but did that
- 16 marketing violate principles in those codes, and
- that was the analysis that I undertook.
- That's why looking at the individual
- behaviors of each company or for each drug were
- important, but at the end of the day, what was most
- important in my analysis was what did the
- 22 marketing -- what was the impact of the marketing,
- why was it done, what impact did it have.
- Q. You talked about -- this may be my
- 25 characterization -- a couple of different ways that

- 1 you could implement or adopt the PhRMA code. Do you
- 2 happen to know specifically how Endo went about
- 3 adopting that code and incorporating it into its
- 4 compliance policies?
- 5 A. So, again, with regard to Endo specifically,
- 6 I didn't do that analysis. I looked at the
- 7 marketing, I looked at the marketing for Opana and
- 8 how that fits into the big picture of marketing for
- 9 opioids, and then assessed whether the marketing of
- opioids adhered to that code.
- 11 Q. Do you understand that Endo took
- 12 disciplinary action against sales representatives
- that failed to adhere to its compliance policies?
- 14 A. I don't have specific examples that I
- recall, but I'm sure that that's consistent with
- 16 what my expectation would be for a pharmaceutical
- 17 company.
- 18 Q. And as part of your analysis, did you review
- 19 Endo's compliance policies?
- 20 A. I know I've reviewed compliance policies but
- I can't specifically cite to an Endo document, no.
- Q. Are you familiar with Endo's policy that it
- only promoted Opana ER to experienced opioid
- 24 prescribers?
- 25 A. I recall from the Opana marketing plans that

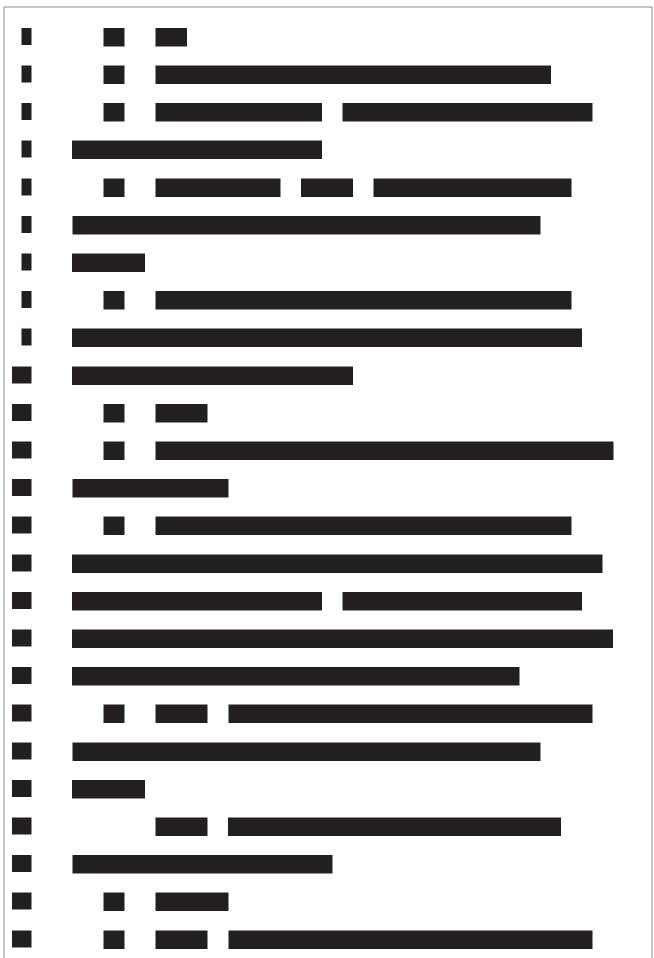
- that was -- that was the strategy that was employed,
- 2 yes.
- Q. Do you agree that experienced opioid
- 4 prescribers are more likely to understand the risks
- 5 associated with opioids?
- 6 MS. BAISCH: Object to form.
- 7 A. That, I don't know for sure. You know, that
- 8 fits into marketing a couple of different ways.
- 9 Experienced prescribers could be high prescribers,
- but they might not be, they might just be more
- 11 experienced. So it would have a different impact on
- 12 the marketing assess -- marketing analysis,
- depending on the outcome of that.
- In terms of the -- whether or not, you know,
- that impacted my analysis of Endo, it was part of
- 16 Endo's marketing but again, I didn't look at Endo's
- marketing, I looked at the marketing of opioids.
- 18 Q. As part of your analysis did you become
- 19 familiar with Endo's internal promotional material
- 20 review process?
- 21 A. I am aware that they have a promotional
- review committee or a process for that. I did not
- 23 undertake to assess the rules their -- the rules of
- the road or the criteria that they use.
- Q. And so you -- fair to say you didn't factor

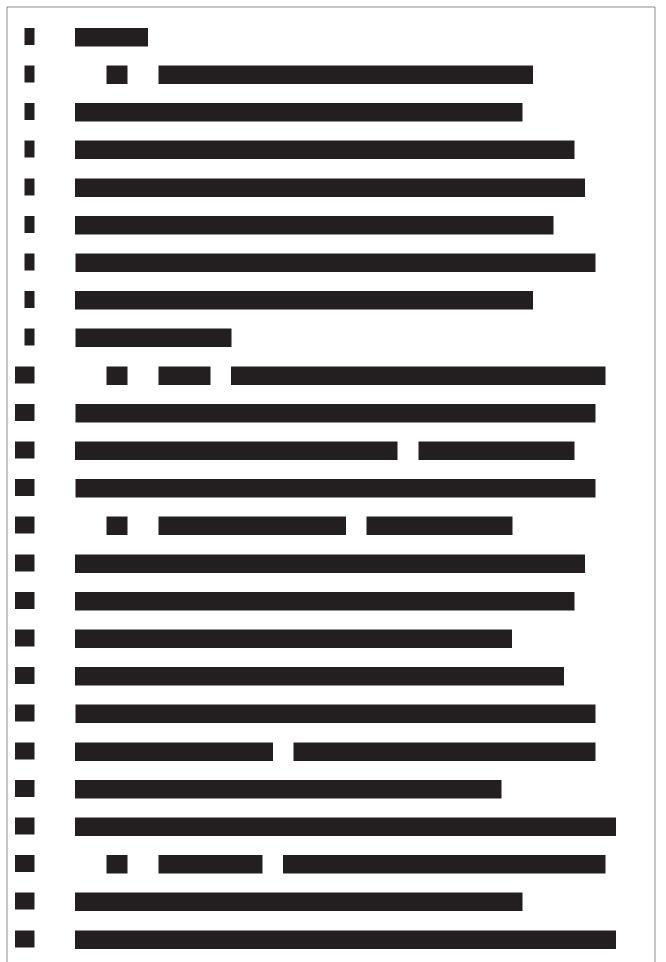
the policies and procedures of that committee into 1 2. your analysis or your opinions? 3 Again, I wasn't looking at the integrity of Α. 4 their marketing messages. I was looking at what the 5 messages were. So I didn't need to undertake that analysis to understand, you know, if it was approved 6 7 or not approved. I assume that anything that made 8 it to market was approved. I know that there are 9 plenty of documents that discuss, you know, this is 10 being forwarded for approval or it's going to be 11 sent, or this has not yet been approved, so don't 12 use it for this or that or the other. 13 Again, the level of analysis that I did 14 was -- that wasn't critical. I needed to understand 15 what messages were used, if they were approved or 16 not approved, okay, but the messages that were 17 employed and what was the impact of those messages. 18 Q. Okay. 19 (Perri Exhibit 34 was marked for 20 identification.) 21 BY MR. HENNESSY: 22

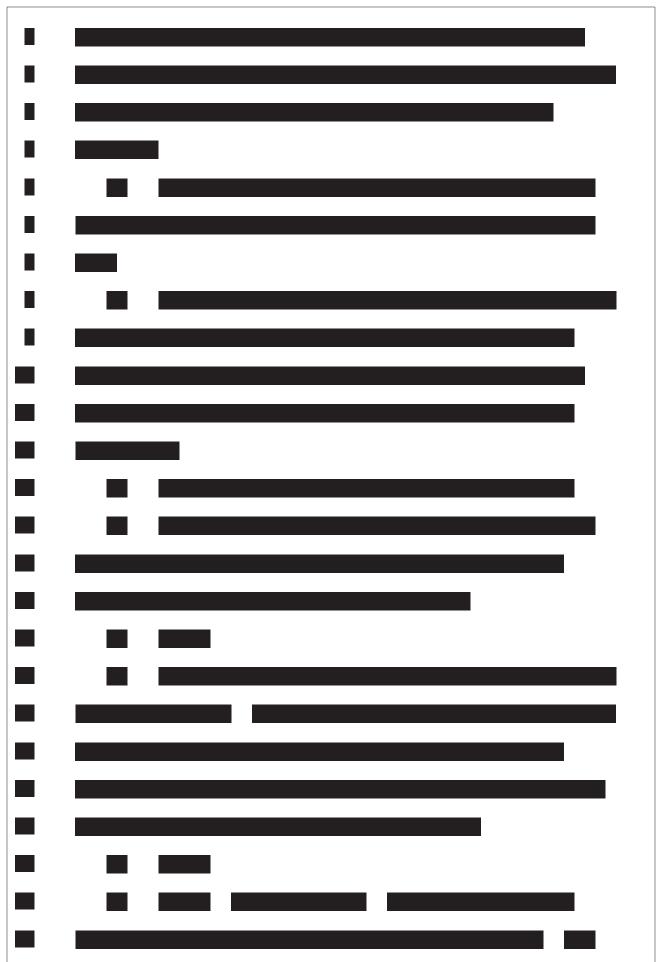


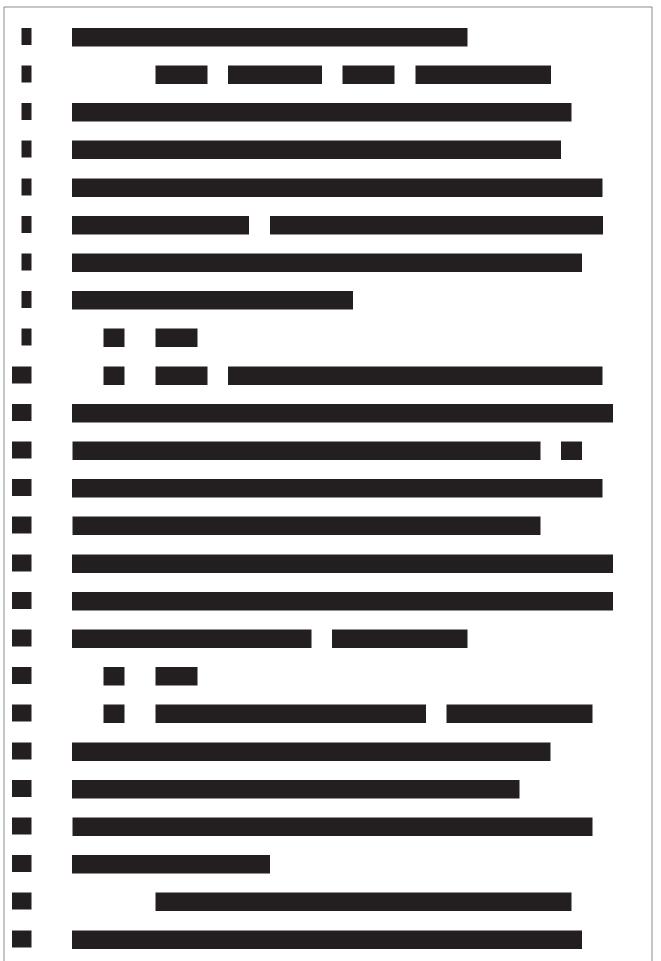










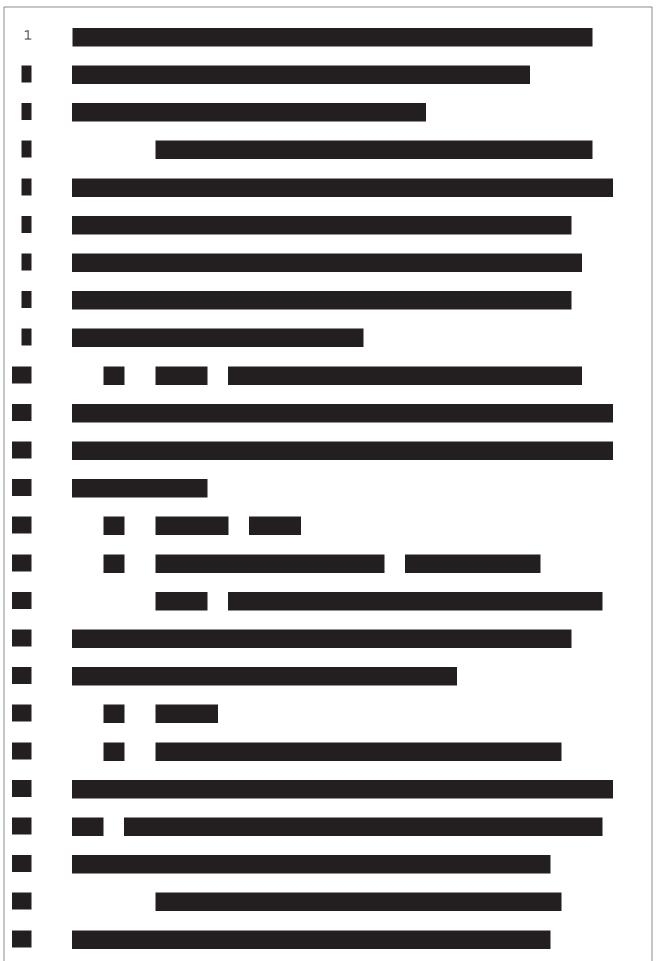


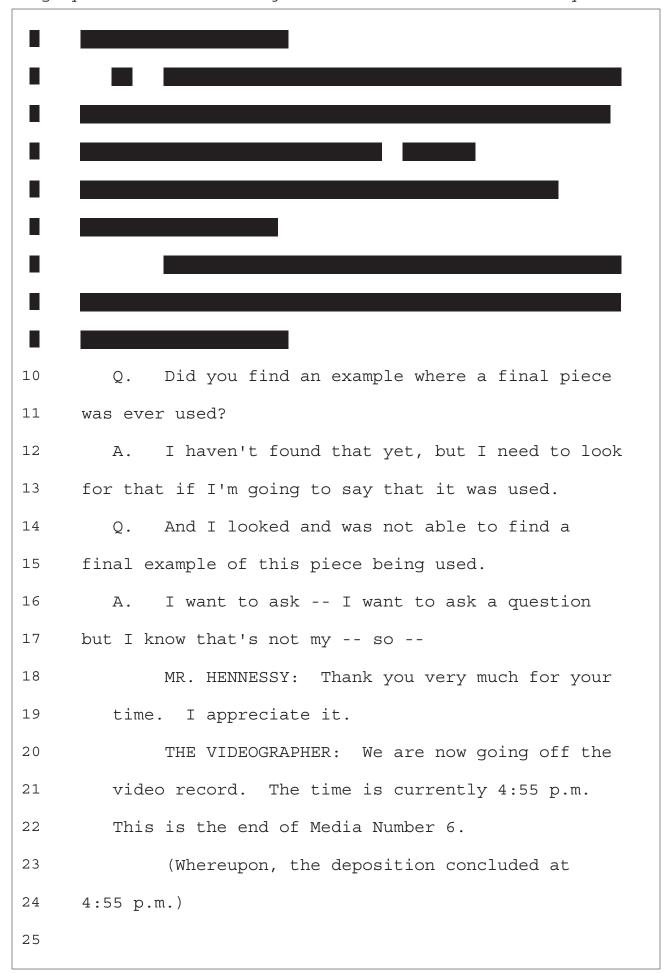
1 7 You can put this one aside for a moment -- I 8 think for good. 9 I'm going to ask you about Table II, 10 although I don't think you need to look at it. I 11 believe you testified that Table II includes 12 references from documents that you know never became 13 live actual marketing documents that were used in 14 the field. Is that fair? 15 I don't know that they were never used in Α. 16 there, but I know they were not used in the form 17 they were presented in Table II, yes. 18 So if they were used --O. 19 They would have been corrected. Α. 20 Q. -- they would have been corrected? 21 Α. Yes. 22 Is it fair to say that Table II Q. Okay. contains other documents that you don't know one way 23 or the other if they ever turned into public 24 25 marketing messages?

1 I -- it's fair to say that there are certainly other documents that didn't make it to 3 market, for example, there are documents related to 4 Moxduo in here, so it's fair to say that there are 5 some but I wouldn't say that it's the predominance of the documents by any means. 6 7 I looked through --8 22 And, you know, as I've been answering 23 questions for the last two days, I've tried to make that clear, that I didn't evaluate the messages from 24 25 a falsehood perspective, it was simply what messages

- 1 were being used.
- 2 So that's why it didn't really matter if it
- 3 was for internal use only or external use. It
- 4 didn't really matter if -- you know, for example,
- with the Endo document in Table II that never got
- 6 used because it was incorrect, it was to simply show
- 7 the processes that were in place and how the
- 8 marketing messages were developed.
- 9 Q. Okay. So to your last point, I looked
- through Table II. By my count there are at least 18
- 11 Endo documents that are internal documents that
- weren't actually approved in final promotional
- pieces, that weren't documents that were ever used
- 14 with doctors.
- 15 A. Okay. Would that include Exhibit 34?
- 16 O. I didn't include Exhibit 34 in there because
- it's a sales training document and those messages
- were delivered to doctors.
- 19 A. Okay.
- 20 Q. These were more of the category of marketing
- 21 plans, other internal use only documents.
- 22 A. Okay. So, again, with any of the
- 23 documents that -- so 18 -- first of all, there are
- 24 hundreds of documents in these table -- in Table II,
- but when you said there were marketing plans, for

- 1 example, the marketing plans would never have been
- 2 expected to be distributed to customers, even though
- 3 they would have contained core messages that might
- 4 have been.
- 5 So we have to be careful not to, you know,
- 6 distort the view of what we're actually looking at,
- 7 messages that were contemplated, messages that were
- 8 implemented, some that were not ever presented to
- 9 customers, I think that's a very small number,
- 10 certainly not 18, and overall, I think we just have
- to understand that this table is simply to identify
- messages that were found in the marketing materials
- without making judgment about those messages.
- Q. If you don't mind, I would just like to ask
- a couple more questions about Table II and I think
- we're close to wrapping up.
- 17 If a message is from an internal document
- and you haven't cited a document where that specific
- message was ever used with a healthcare provider, is
- it fair to say that you're not going to offer the
- opinion that that statement from the internal
- document influenced any prescribing decision?
- A. Yes, I absolutely agree with that. I would
- 24 never make that quantum leap, that a message that
- was never presented to a customer influenced





1 CERTIFICATE 2. I, SUSAN D. WASILEWSKI, Registered Professional Reporter, Certified Realtime Reporter 3 4 and Certified Realtime Captioner, do hereby certify 5 that, pursuant to notice, the deposition of MATTHEW PERRI, III, BS Pharm, Ph.D., RPh, was duly taken on 6 7 Wednesday, April 24, 2019, at 8:35 a.m. before me. 8 The said MATTHEW PERRI, III, BS Pharm, Ph.D., RPh, was duly sworn by me according to law to tell 9 10 the truth, the whole truth and nothing but the truth 11 and thereupon did testify as set forth in the above 12 transcript of testimony. The testimony was taken 13 down stenographically by me. I do further certify 14 that the above deposition is full, complete, and a 15 true record of all the testimony given by the said 16 witness, and that a review of the transcript was 17 requested. 18 19 20 Susan D. Wasilewski, RPR, CRR, CCP 21 (The foregoing certification of this transcript does 22 not apply to any reproduction of the same by any 23 means, unless under the direct control and/or supervision of the certifying reporter.) 24 25

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                     INSTRUCTIONS TO WITNESS
 2.
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              Please read your deposition over carefully
 5
      and make any necessary corrections. You should
      state the reason in the appropriate space on the
 6
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      errata sheet for any corrections that are made.
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              After doing so, please sign the errata sheet
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      and date it. It will be attached to your
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      deposition.
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              It is imperative that you return the
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      original errata sheet to the deposing attorney
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      within thirty (30) days of receipt of the deposition
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      transcript by you. If you fail to do so, the
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      deposition transcript may be deemed to be accurate
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      and may be used in court.
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Case: 1:17-md-02804-DAP_Doc#: 1983-5 Filed: 07/24/19 318 of 320. PageID #: 244350. Further Confidentiality Review

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2	ERRATA	
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4	PAGE LINE CHANGE	
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1	ACKNOWLEDGMENT OF DEPONENT
2	
3	I,, do hereby
4	acknowledge that I have read the foregoing pages,
5	352 through 669, and that the same is a correct
6	transcription of the answers given by me to the
7	questions therein propounded, except for the
8	corrections or changes in form or substance, if any,
9	noted in the attached Errata Sheet.
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13	MATTHEW PERRI, III, BS Pharm, Ph.D., RPh DATE
14	
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18	Subscribed and sworn to before me this
19	day of, 20
20	My Commission expires:
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22	Notary Public
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Case: 1:17-md-02804-DAP_Doc#: 1983-5 Filed: 07/24/19 320 of 320 PageID #: 244352. Filed: 07/24/19 320 of 320 PageID #: 244352.

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